PB84-210335

Guidance for the Reregistration of Manufacturing-Use and Certain End-Use Pesticide Products Containing Terbufos as the Active Ingredient

(U.S.) Environmental Protection Agency
Washington, DC

Jun 83

U.S. Department of Commerce
National Technical Information Service
NTIS

PB84-210335

GUIDANCE FOR THE REREGISTRATION OF MANUFACTURING-USE AND CERTAIN END-USE PESTICIDE PRODUCTS CONTAINING TERBUFOS AS AS THE ACTIVE INGREDIENT

June 1983

EPA-540/RS-83-011

Office of Pesticides and Toxic Substances

Environmental Protection Agency
401 M. St. SW
Washington, DC 20460

REPRODUCED BY
NATIONAL TECHNICAL
INFORMATION SERVICE
U.S. DEPARTMENT OF COMMERCE
SPRINGFIELD, VA. 22161

50272-101

REPORT DOCUMENTATION PAGE

1. REPORT NO.

2.

3. Recipient's Accession No. PB8[illegible] 210335

4. Title and Subtitle

Guidance for Reregistration of
Pesticide Products Containing TERBUFOS
As the Active Ingredient

5. Report Date 6/83

6.

7. Author(s)

USEPA, Office of Pesticide Programs,
~~Registration Division~~

8. Performing Organization Rept. No. 540/RS-83-011

9. Performing Organization Name and Address

Environmental Protection Agency
Office of Pesticide Programs
401 M. St. SW (TS-767c)
Washington, DC 20460

10. Project/Task/Work Unit No.

11. Contract(C) or Grant(G) No.

(C)

(G)

12. Sponsoring Organization Name and Address

same as #9

13. Type of Report & Period Covered

14.

15. Supplementary Notes

16. Abstract (Limit: 200 words)

This document contains information regarding reregistration of pesticide products containing the subject active ingredient. The document includes how to register under a registration standard, regulatory position and rationale, and summaries of data requirements and data gaps. Also included is a bibliography containing citations of all studies reviewed by EPA in arriving at the positions and conclusions contained in the standard.

17. Document Analysis a. Descriptors

b. Identifiers/Open-Ended Terms

c. COSATI Field/Group

18. Availability Statement:

19. Security Class (This Report)

20. Security Class (This Page)

21. No. of Pages 95

22. Price

(See ANSI-Z39.18)

See Instructions on Reverse

OPTIONAL FORM 272 (4-77)
(Formerly NTIS-35)
Department of Commerce

Table of Contents

Section Page

I. Introduction 1

II. Regulatory Position and Rationale. 3

III. Requirement for Submission of Generic Data 20

IV. Requirement for Submission of Product-Specific Data 49

V. Submission of Revised Labeling and Packaging Information. 50

A. Label Contents 50

1. Product Name 50
2. Company Name and Address 50
3. Net Contents 51
4. Product Registration Number. 51
5. Producing Establishment Registration Number. 51
6A Ingredient Statement 51
6B Pounds Per Gallon Statement. 51
7. Front Panel Precautionary Statements 51
7A Child Hazard Warning Statements. 52
7B Signal Word. 52
7C Skull and Crossbones and Word Poison 52
7D Statement of Practical Treatment 52
7E Referral Statement 52
8. Side/Back Panel Precautionary Labeling 52
8A Hazard to Humans and Domestic Animals. 53
8B Environmental Hazard 53
8C Physical or Chemical Hazard. 53
9 Misuse Statement 54
10A Storage and Disposal Block 54
10B Directions for Use 54

B. Collateral Information 54

VI. Instructions for Submission. 55

APPENDICES

III-1 Bibliography. 56

III-2 FIFRA §3(c)(2)(B) Summary Sheet 70

III-3 Certification of Attempt to Enter Into an Agreement With Other Registrants for Development of Data. . . . 71

IV-1 Product Specific Data Report (End-Use Products) . . . 72

V-2 Table of Labeling Requirements. 74

V-3 Physical/Chemical Hazards Labeling Statement. 78

V-5 Storage and Disposal Instructions 79

Note: Appendices V-1, V-4, and V-6 are not germane to this document and are not included.

I. INTRODUCTION

The Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) Section 3(g), as amended in 1978, directs the Environmental Protection Agency (EPA) to reregister all currently registered products as expeditiously as possible. Each registrant of a currently registered product who wishes to continue to sell or distribute that product in commerce must apply for reregistration.

This guidance document sets forth certain of the requirements for registration and reregistration of all manufacturing-use products (MPs) containing the subject chemical as the sole active ingredient. These requirements include: that certain scientific data be submitted and that certain standards of toxicity, composition, labeling, and packaging be met. Registrants of MPs are referred to all Sections and Tables for specific information regarding their responsibilities under this guidance document.

This guidance document also sets forth the data requirements for those end-use products which contain the subject active ingredient and for which the source of that active ingredient is (1) not registered with EPA or (2) produced by the registrant's firm, or a firm which has ownership in common with the registrant's firm, or (3) both (1) and (2). Registrants of such end-use products can exempt themselves from these requirements if they change their source of supply to a registered source, provided the source (i.e., registered active ingredient product) is obtained from a firm that does not share ownership in common with the registrant's firm. (If the end-use product registrant decides to switch sources, a new confidential statement of formula, EPA Form 8570-4, must be submitted to the appropriate Product Manager within 90 days of receipt of this guidance document.) Registrants of affected end-use products are referred to only Sections II, III, and VI and Table A for specific information regarding their responsibilities under this guidance document.

It should be noted that end-use products containing the subject active ingredient will not be reregistered at this time. Any necessary labeling changes will be implemented under the Agency's Label Improvement Program at a future time.

EPA will issue a notice of intent to cancel or suspend the registration of any currently registered product if the registrant fails to comply with the requirements set forth in this guidance document and with the requirements contained in subsequent information from EPA about compliance with certain data support requirements.

This guidance document has been prepared to provide registrants with specific information on how they may reregister their manufacturing-use products or maintain their end-use products' registration. (Refer to the cover letter's attachment for a listing of your affected products.) If for any reason you decide to request that the Agency discontinue the registration of any of your products subject to the registration requirements in this document, please notify the Product Manager named in the cover letter, within 90 days from the receipt of this document, that you wish to voluntarily cancel the registration(s). If you decide to maintain your product registration(s), you must provide the information described in the following pages within the timeframes outlined.

Registrants are reminded that Section 6(a)(2) of FIFRA requires you at any time to submit factual information raising concerns of possible unreasonable adverse effects of a pesticide. You should notify the Agency of interim results of studies in progress if those results show possible adverse effects.

This guidance document will be supplemented by EPA with additional information about compliance with data support requirements. In Monsanto v. Administrator, EPA was recently enjoined by the District Court for the Eastern District of Missouri from implementing in any way the "mandatory data licensing" aspects of §3(c)(1)(D) of FIFRA. EPA is assessing the implications of the injunction for the reregistration process. Because this situation is currently unresolved, EPA has decided to proceed with the requirements in this guidance package which do not relate to the "data licensing" issue and to supplement the package with additional guidance when circumstances permit.

II. REGULATORY POSITION AND RATIONALE

A. INTRODUCTION

This Registration Standard describes the regulatory position of the Environmental Protection Agency (EPA) on manufacturing use products (MPs) containing the insecticide-nematicide terbufos. The Agency's position is based on an evaluation of all registered uses and registered MPs with terbufos as the sole active ingredient. There are no products registered that contain terbufos in a mixture with other active ingredients. This position is based on a number of considerations. Foremost among these is an analysis of terbufos data based on the risk criteria found in Section 162.11(a) of Title 40 of the U.S. Code of Federal Regulations. The Standard also considers labeling requirements, tolerances, "Special Local Needs" registrations authorized by Section 24(c) of the FIFRA as well as federal registrations granted under Section 3 of the FIFRA. Finally, the Agency sets forth the data requirements that must be met to register or reregister products covered by the Standard.

This Standard only addresses registration requirements for current or substantially similar future MPs and their intermediaries. Terbufos MPs that differ appreciably from those described here may require amendments to the Standard. Additionally, use patterns which differ from those described here may also require amendments to the Standard.

B. USE PROFILE

Terbufos is the acceptable common name for S-[[(1,1-dimethylethyl)thio] methyl]O,O-diethyl phosphorodithioate recognized by the American National Standards Institute, British Standards Institution, New Zealand and International Organization for Standardization. Trade names and other names for terbufos are: Counter®, CL 92100, AC 92100, ENT 97920, and ST 100.

American Cyanamid Company, Agricultural Division is currently the sole manufacturer of the technical product and formulator of granular end-use products in the U.S.A.

Terbufos, an organophosphate chemical, is principally used as an insecticide for corn rootworms on corn and is applied as a soil incorporated product at planting and at post-emergence. Other uses include use as a nematocide for lesion, spiral, stunt, sting, stubby-root and dagger nematodes on corn; and as an insecticide for greenbugs on grain sorghum, sugarbeet root maggot on sugarbeets, and seedcorn maggots, symphylans, wireworms, maize billbug, southern corn billbug and reduction of white grubs on corn.

There are two federal registrations for products containing terbufos: one, an MP containing 85.0% terbufos, the other, an end-use granular product containing 15.0%. There are several Special Local Need Registrations which were issued for 15% granular products.

C. REGULATORY POSITION

Based on a review and evaluation of available data and other relevant information on the chemical, the Environmental Protection Agency has made the following determinations regarding terbufos:

1. Manufacturing - use pesticide products containing terbufos as a sole active ingredient or mixed with other active ingredients may be registered for sale, distribution, and use, subject to the terms and conditions specified in this Standard.

2. Based on available data, the Agency has determined that terbufos has not been demonstrated to cause unreasonable adverse effects in man when used in accordance with prescribed label directions and precautions.

   However, the safety of this chemical cannot be adequately addressed at the present time due to extensive data gaps.

3. The review has identified potential environmental concerns. Results of available laboratory studies indicate a very high acute toxicity to fish and aquatic invertebrates. The SWRRB* and EXAMS** models predict

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* SWRRB is a hydrology model combined with a pesticide runoff model.

** EXAMS is a hydrologic model to predict "steady-state" and "pulse-load" behavior of organic toxicants in aquatic ecosystems.

aquatic concentrations of terbufos in excess of the LC_{50} for aquatic organisms. In order to determine whether significant evidence relating to aquatic organisms would raise prudent concerns of unreasonable adverse risk to the environment, the Agency is requiring further monitoring of water, sediment, and fish; in ponds adjacent to treated fields. The Agency will also conduct additional modeling utilizing various parameters. Once the Agency has evaluated these additional data, it will determine whether the Agency should initiate a public interim review process by placing the chemical in special review. If, instead, regulation of the chemical through the normal registration process is found to be appropriate, the Agency will update its regulatory position and rationale to reflect this conclusion and the reasoning behind it.

4. A May 19, 1983 Biological Opinion from the Office of Endangered Species (OES), Fish and Wildlife Service, U.S. Department of Interior, predicted that the use of terbufos on corn is "...likely to jeopardize the continued existence ..." of a variety of federally-listed endangered/threatened species. These species include three species of birds, two species of fish, twelve aquatic invertebrate species and two insect species. Consultation for an opinion

from OES has recently been initiated for use on sorghum; and consultation for sugar beets may be initiated, if it is deemed necessary. Labeling and/or other alternatives, as appropriate will be prescribed by the Agency based on the biological opinions received from OES for the use of terbufos on corn, sorghum and sugar beets.

5. Based on available information, there appears to be a potential for substantial hazard to terrestrial organisms from the use of terbufos as described in this Standard. This is based on the availability of granules to wildlife at and below the soil surface, the high to very high acute toxicity of terbufos to terrestrial organisms, and the record of field kills with other granular products of similar toxicity. Additional avian and mammalian testing including actual field testing are needed to fully assess this hazard potential.

6. Registrants must provide or agree to develop additional data, as specified in Tables A and B located in Chapter IV of this document, in order to maintain existing registrations or to permit new terbufos registrations.

7. Tolerance reassessment is normally a part of the Registration Standard review process. Because essential toxicology data are not available, the Agency is unable

to complete its reassessment of terbufos tolerances. Specifically, due to the extensive data gaps the Agency is unable to establish a valid "No Observable Effect Level" (NOEL) or determine an Acceptable Daily Intake (ADI) for terbufos.

The tolerances listed under 40 CFR 180.352 for terbufos are currently set for " .....combined residues of the insecticide terbufos.....and its cholinesterase-inhibiting metabolites.....". This wording will be revised to read ".....phosphorylated (cholinesterase-inhibiting) metabolites....." as specified in Section H.

8. On August 1, 1979, a notice was published in the Federal Register (44 FR 45219) of a proposal to amend 40 CFR 162.31 by assigning the granular formulations of several pesticide chemicals a restricted use classification under the optional classification by regulation procedures pursuant to 40 CFR 162.30. On August 7, 1979 (44 FR 46303) this notice was corrected to include granular formulations of terbufos, on the basis of acute oral, and dermal toxicity and residue effects on avian species. A final classification determination of the end-use formulations containing terbufos will be made by the Agency pursuant to these optional classification by regulation procedures.

D. REGULATORY RATIONALE

Terbufos, a cholinesterase-inhibiting chemical has a high acute toxicity to humans. The available acute studies indicate that the chemical is in Toxicity Category I for both the oral and dermal routes of exposure. The acute inhalation toxicity remains to be determined pending receipt and review of the requested rat LC_{50} inhalation testing.

The Agency has determined that it should continue to allow registration of terbufos for the following reasons:

1. The stringent label warning statements reflecting the high acute toxicity to humans which include directions for use of protective clothing including gloves, goggles, and a mask or respirator will minimize the acute hazards to users of the manufacturing use product associated with the oral, dermal, inhalation and ocular routes of exposure. The registered manufacturing use product described in this Standard, a liquid product, bears such stringent warning statements.

   The granular composition of the end-use product as described in this Standard together with the recommended stringent label precautions which include the use of gloves, goggles, and protective clothing, will minimize the acute hazards to loader/ applicators through the oral, dermal and ocular routes of exposure. Due to the size of the granulars and the method of application (soil incorporation), exposure through inhalation from use of the end-use product is not expected. The end-use product for terbufos as described in this Standard is intended for outdoor, nondomestic use only, and bears the label restriction, "not for use or storage in or around the home".

Because the end-use product is of a granular composition, and because the current registered use patterns require soil incorporation, there is little potential for worker re-entry exposure. Consequently, no re-entry data are required to support current registered uses described in this Standard and no re-entry interval as defined in 40 CFR 170.2 of Part 170, Worker Protection Standards for Agricultural Pesticides would be required for these current uses.

2. Based on available data, terbufos is not expected to leach into ground water.

3. Terbufos was first registered in 1974 for use in corn fields to control corn rootworms. The Pesticide Incident Monitoring System (PIMS) records through June, 1981, include 31 reports involving terbufos, of which 19 involved terbufos alone. Of these 19 incidents, 9 involved humans; 8 involved domestic livestock and 2 involved wildlife. No human fatalities resulted. In those human exposure incidents which were reported with some detail, it appears that carelessness or

negligence were important factors. In two of these incidents, the granular pesticide was reported to have been handled with bare hands during loading and application procedures.

In those instances involving livestock, one resulted in the death of about 600 cattle, another in the death of 127 cattle. The accidental contamination of livestock feed was reported as the cause in these incidents. The two wildlife instances involved fish kills which were reportedly due to runoff from treated fields. Only one included analysis of the water samples. Though the sampling agency was unable to test for terbufos, no evidence of organophosphorous compounds was found in the sampled water.

Carelessness and/or negligence appear to have been important factors in most incidents. Strict adherence to proper storage and application techniques as prescribed in the label directions and precautions will minimize the risk of potential adverse effects to humans and domestic animals.

4. It is not the Agency's policy to cancel or to withhold registration merely because data are missing or inadequate [see FIFRA Sections 3(c)(2)(B) and 3(c)(7)]. Rather, publication of this Standard provides a mechanism for identifying data needs, and registration of terbufos under this standard allows for the upgrading of labels

during the period in which the required data are being developed. These data will be reviewed and evaluated when they are received and the agency will determine, at that time whether they will affect the registration(s) of terbufos.

E. CRITERIA FOR REGISTRATION UNDER THIS STANDARD

To be covered by this Standard, products must:

- Contain terbufos as the sole active ingredient or in combination with other active ingredients in a mixture,
- Bear required labeling, and
- Conform to the acute toxicity limits, product composition, and use pattern requirements listed in Section F of this Standard.

The applicant for registration or reregistration of products subject to this standard must comply with all terms and conditions described in it. That includes making a commitment to fill data gaps on a schedule agreed to by both this agency and the applicant. Applicants for registration under this Standard must follow the instructions contained in this guidance package and complete and submit the appropriate forms within the time specified.

F. ACCEPTABLE RANGES AND LIMITS

1. Product Composition

To be covered under this Standard, technical grade products must contain at least 85 percent terbufos as the sole active ingredient. Each manufacturing use product formulation proposed for registration must be fully described with appropriate certification of limits.

2. Acute Toxicity Limits

The Agency will consider registration of technical grade and manufacturing-use products containing terbufos for acute Toxicity Category I,II,III, or IV provided that the labeling of these products bears appropriate precautionary statements.

3. Use Patterns

To be registered under this Standard manufacturing use products containing terbufos may be labeled for formulation only into end-use products for outdoor, non-domestic use on corn (field, sweet or pop), sugar beets or grain sorghum.

End-use products formulated from products registered under this Standard must be granular formulations for ground incorporated application. Other formulation types or other methods of application may require amendments to this Standard.

G. REQUIRED LABELING:

All technical grade, manufacturing - use, and end-use products containing terbufos must bear appropriate labeling as specified in 40 CFR 162.10. Other portions of the guidance package contain specific information regarding label requirements. Both the currently registered manufacturing-use and end-use products are in Toxicity Category I and, as such must bear appropriate precautionary labeling as designated in 162.10 for this high toxicity category including the word Poison (in red) and the skull and crossbones. Statements instructing use of protective clothing, including gloves and goggles, must also appear on all labeling.

1. Manufacturing-Use

In addition to the labeling as described above, the labels of all manufacturing-use products must contain the following statements:*

- "Wear protective clothing, rubber gloves and goggles."
- "Wear a pesticide respirator jointly approved by the Mining Enforcement and Safety Administration (formerly the U.S. Bureau of Mines) and by the National Institute

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*It should be noted that the labeling for the current registered MP already contains the required Category I labeling as well as the protective clothing, rubber gloves, goggles and respirator statements.

for Occupational Safety and Health under the provision of 30 CFR Part 11 for organic phosphate protection.

- "For formulation into end-use insecticide products intended for non-domestic outdoor terrestrial use on (crops to be specified)".

- "This pesticide is toxic to fish and wildlife. Do not discharge into lakes, streams, ponds, or public waters unless in accordance with an NPDES permit. For guidance contact your Regional Office of the Environmental Protection Agency".

2. End-Use Products

Though this Standard does not address registration/reregistration requirements for end-use products, the following labeling recommendations are being made at this time based on current use patterns and based on review of available data. Additional labeling statements may be needed upon receipt and evaluation of the data requested in this Standard.

In addition to the Toxicity Category I labeling as designated in 40 CFR 162.10, the labels must contain the statements:*

- "Wear protective clothing, gloves and goggles."

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*It should be noted that, with the exception of the recommendation to wear goggles, these statements, or similar wording already appear on the current registered labeling along with the required Toxicity Category I labeling.

- "Not for use or storage in or around the home."
- "This pesticide is toxic to fish and wildlife. Treated granules exposed on soil surface may be hazardous to birds and other wildlife. Do not apply directly to water or wetlands. Runoff from treated areas may be hazardous to aquatic organisms in neighboring areas. Do not contaminate water by cleaning of equipment or disposal of wastes. Cover or incorporate granules that are spilled."

Appropriate labeling, if necessary will be prescribed by the Agency based on the biological opinions received from the Office of Endangered Species, U.S. Fish and Wildlife Service.

H. TOLERANCE REASSESSMENT

Tolerances have been established for corn, sugar beets and grain sorghum under 40 CFR 180.352. There are currently no food or feed additive tolerances and it has been determined that none are required for food and/or feed byproducts of these commodities. Canada has established tolerances on sugar beets and corn on a negligible residue basis, i.e., at less than 0.1 ppm in human food. There are no Mexican tolerances or Codex Maximum Residue Limits for these crops. Refer to the tolerance summary table at the end of this section.

Based on available data, it has been determined that the establishment of a crop group tolerance is not appropriate, at any level, for the crop groupings to which these crops belong, i.e., root and tuber vegetable group (sugar beets), and cereal grains group (corn and sorghum).

There are no tolerances for meat, milk, poultry and eggs, and none are required to support the current established tolerances on sugar beets, corn and sorghum. There is no reasonable expectation of finite residues occuring in these foods from feed use of these raw agricultural commodities including their processing byproducts. Requests for new livestock feed crops, however, may require tolerances for meat, milk, poultry and eggs.

The established tolerances for terbufos are presently expressed in terms of terbufos and its cholinesterase-inhibiting metabolites without specifying the latter as phosphorylated metabolites. The Agency will proceed towards revising 40 CFR 180.352 by changing the wording to read ".....terbufos.....and its phosphorylated (cholinesterase-inhibiting) metabolites:

- Phosphorothioic acid, S-(t-butyl-thio) methyl O,O-diethyl ester.
- Phosphorothioic acid, S-(t-butyl-sulfinyl) methyl O,O-diethyl ester.
- Phosphorothioic acid, S-(t-butyl-sulfonyl) methyl O,O-diethyl ester.
- Phosphorodithioic acid, S-(t-butyl-sulfinyl) methyl O,O-diethyl ester.
- Phosphorodithioic acid, S-(t-butyl-sulfonyl) methyl O,O-diethyl ester."

Reassessment of the established terbufos tolerances must await receipt and evaluation of the pertinent toxicological studies as requested on the accompanying Tables A and B. Available chronic toxicity studies are only supplementary data and thus may not be used as a basis for tolerance assessment. Consequently, a "No Observable Effect Level" (NOEL) cannot be established at the present time, hence a maximum permissible intake (MPI) cannot be calculated.

Summary of present tolerances for terbufos.

	Canada	Mexico	Codex	U.S
Beets, sugar, roots	0.1*	-	-	0.05
Beets, sugar, tops	0.1*	-	-	0.10
Corn, field, fodder	0.1*	-	-	0.5
Corn, field, forage	0.1*	-	-	0.5
Corn, pop, fodder	0.1*	-	-	0.5
Corn, pop, forage	0.1*	-	-	0.5
Corn, grain	0.1*	-	-	0.05
Corn, sweet (K+CWHR)	0.1*	-	-	0.05
Corn, sweet, forage	0.1*	-	-	0.5
Corn, sweet, fodder	0.1*	-	-	0.5
Sorghum, fodder	-	-	-	0.5
Sorghum, forage	-	-	-	0.5
Sorghum, grain	-	-	-	0.05

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*Negligible residue basis, i.e., at less than 0.1 ppm in human food.

III. REQUIREMENT FOR SUBMISSION OF GENERIC DATA

A. This portion of the guidance document is a Notice issued under the authority of FIFRA Section 3(c)(2)(B) and describes, in table format, the data required for maintaining the registrability of each product. Additionally, a bibliography (Appendix III-1) is included that identifies that data considered as part of the data base supporting this standard. EPA has determined that additional generic data described in this Notice must be submitted to EPA for evaluation in order to maintain in effect the registration(s) of your product(s) identified as an attachment to the cover letter accompanying this guidance document. As required by FIFRA Section 3(c)(2)(B), you are required to take appropriate steps to comply with this Notice.

EPA may suspend the registration of each of those products unless, within the specified time, you have informed EPA how you will satisfy the requirements of this Notice. Any such suspension will remain in effect until you have complied with the terms of this Notice.

B. What Generic Data [1] Must Be Submitted. You may ascertain which generic data you must submit by consulting Table A at the end of this section. That table shows all the generic data needed to evaluate the continued registrability of all products, and the dates by which the data must be submitted. The required data must be submitted and any necessary studies must be conducted in accordance with EPA-approved protocols, the Pesticide Registration Guidelines 2/, or data collected under the approved protocols of the Organization for Economic Cooperation and Development (OECD). If you wish not to develop data which are necessary to support the registration or reregistration of certain uses appearing in your labeling, you may delete those uses at the time you submit your revised labeling.

Also for certain kinds of testing (generally ecological effects), EPA requires the test substance to be a "typical formulation," and in those cases EPA needs data of that

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1/ Generic data pertain to the properties or effects of a particular ingredient, and thus are relevant to an evaluation of the risks of all products containing that ingredient (or all such products having a certain use pattern), regardless of any such product's unique composition or use. Product-specific data relate only to the properties or effects of a product with a particular composition (or a group of products with closely similar composition).

2/ The Pesticide Registration Guidelines were reproposed on November 24, 1982 in 47 Federal Register 53192.

type for each major formulation category (e.g., emulsifiable concentrates, wettable powders, granulars, etc.) These are classified as generic data and when needed are specified in Table A. EPA may possess data on certain "typical formulations" but not others. Note: The "typical formulation" data should not be confused with product-specific data (Table B) which are required on each formulation. Product-specific data are further explained in Section IV of this document.

C. Options Available for Complying With Requirements to Submit Data

Within 90 days of your receipt of this Notice you must submit to EPA a completed copy of the form entitled "FIFRA Section 3(c)(2)(B) Summary Sheet" [EPA Form 8580-1, Appendix III-2] for each of your products. On that form you must state which of the following methods you will use to comply with the requirements of this Notice:

1. (a) Notify EPA that you will submit the data, and

   (b) either submit the existing data you believe will satisfy the requirement, or state that you will generate the data by conducting testing. If the test procedures you will use deviate from (or are not specified in) the Registration Guidelines or protocols contained in the Reports of Expert Groups to the Chemicals Group, Organization for Economic Cooperation and Development (OECD) Chemicals Testing Programme, you must enclose the protocols you will use.

2. Notify EPA that you have entered into an agreement with one or more other registrants to jointly develop (or share in the cost of developing) the data. If you elect this option, you must notify EPA which registrant(s) are parties to the agreement.

3. File with EPA a completed "Certification of Attempt to Enter Into an Agreement With Other Registrants for Development of Data" (EPA Form 8580-6, Appendix III-3)*/

4. Request that EPA amend your registration by deleting the uses for which the data are needed. (This option is not available to applicants for new products.)

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*/ FIFRA Section 3(c)(2)(B) authorizes joint development of data by two or more registrants, and provides a mechanism by which parties can obtain an arbitrator's decision if they agree to jointly develop data but fail to agree on all the terms of the agreement. The statute does not compel any registrant to agree to develop data jointly.

(Footnote continued at bottom of next page)

5. Request voluntary cancellation of the registration(s) of your products for which the data are needed. (This option is not available to applicants for new products.)

D. Procedures for Requesting Changes in Testing Methodology and Extensions of Time

EPA recognizes that you may disagree with our conclusions regarding the appropriate ways to develop the required data or how quickly the data must be submitted. If the test procedures you plan to use deviate from (or are not specified in) the registration guidelines or protocols contained in the reports of the Expert Groups to the Chemical Groups, Organization for Economic Cooperation and Development (OECD) Chemicals Testing Programme, you must submit the protocol for Agency review prior to the initiation of the test.

If you think that you will need more time to generate the required data than is allowed by EPA's schedule, you may submit a request for an extension of time. The extension request must be submitted in writing to the Product Manager. The extension request should state the reasons why you conclude that an extension is appropriate. While EPA considers your request, you must strive to meet the deadline for submitting the required data.

(Footnote continued from previous page)

In EPA's opinion, joint data development by all registrants who are subject to the requirements to submit a pertinent item of data or a cost-sharing agreement among all such registrants is clearly in the public interest. Duplication of testing could increase costs, tie up testing facilities, and subject an unnecessarily large number of animals to testing.

As noted earlier, EPA has discretion not to suspend the registration of a product when a registrant fails to submit data required under FIFRA Section 3(c)(2)(B). EPA has concluded that it is appropriate to exercise its discretion not to suspend in ways which will discourage duplicative testing. Accordingly, if (1) a registrant has informed us of his intent to develop and submit data required by this Notice; and (2) a second registrant informs EPA that it has made a bona fide offer to the first registrant to share in the expenses of the testing [on terms to be agreed upon or determined by arbitration under FIFRA Section 3(c)(2)(B)(iii)]; and (3) the first registrant has declined to agree to enter into a cost-sharing agreement, EPA will not suspend the second firm's registration. While the first firm is not required to agree to jointly develop data, EPA is not required to force the second firm to engage in economically inefficient duplicative testing in order to maintain its registration.

TABLE A
GENERIC DATA REQUIREMENTS FOR TERBUFOS

Data Requirement	Composition 1/	Does EPA Have Data To Satisfy This Requirement? (Yes, No or Partially)	Bibliographic 5/ Citation	Must Additional Data Be Submitted Under FIFRA Section 3(c)(2)(B)? 2/
§158.120 Product Chemistry				
Product Identity:				
61-2 - Statement of Composition	TGAI	Partial	00085161*	Yes 3/
61-3 - Discussion of Formation of Ingredients	TGAI	Yes	00069499* 4/ 00085160* 4/ 00087711* 4/	No
Analysis and Certification of Product Ingredients				
62-1 - Preliminary Analysis	TGAI	Yes	00040389*	No
Physical and Chemical Characteristics				
63-2 - Color	TGAI	Yes	00040385*	No
63-3 - Physical State	TGAI	Yes	00040385*	No
63-4 - Odor	TGAI	Yes	00040385*	No
63-5 - Melting Point	TGAI	Yes	00040385*	No
63-6 - Boiling Point	TGAI	Partial	00040385* 00036234*	Yes 7/
63-7 - Density, Bulk Density, or Specific Gravity	TGAI	Yes	00040385*	No

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* Data submitted by American Cyanamid. These data may be compensable.

TABLE A
GENERIC DATA REQUIREMENTS FOR TERBUFOS

Data Requirement	Composition 1/	Does EPA Have Data To Satisfy This Requirement? (Yes, No or Partially)	Bibliographic Citation 5/	Must Additional Data Be Submitted Under FIFRA Section 3(c)(2)(B)? 2/
§158.120 Product Chemistry (continued)				
63- 8 - Solubility	TGAI OR PAI	Partial	00040385*	Yes 6/
63- 9 - Vapor Pressure	TGAI OR PAI	Partial	00040385*	Yes 7/
63-10 - Dissociation constant	TGAI OR PAI	Not Applicable	-	-
63-11 - Octanol/water partition coefficient	PAI	No	-	Yes
63-12 - pH	TGAI	No	-	Yes
63-13 - Stability	TGAI	Yes	00087716*	No
Other Requirements:				
64- 1 - Submittal of samples	Choice	-	-	No 8/

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* Data submitted by American Cyanamid. These data may be compensable.

TABLE A
GENERIC DATA REQUIREMENTS FOR TERBUFOS

§158.120 Product Chemistry (continued)

1/ Composition: TGAI = Technical grade of the active ingredient; PAI = Pure active ingredient; Choice = Choice of several test substances determined on a case-by-case basis.
2/ Data must be submitted no later than December, 1983.
3/ Further information is needed on the composition of starting materials.
4/ Any one of these citations are adequate to meet this data requirement.
5/ These data citations pertain to the technical terbufos currently registered under EPA Reg. No. 241-241 and may not be applicable to technical terbufos material which differs from that described herein.
6/ Solubility in quantitative terms for solvents other than water is needed.
7/ Clarification is needed on the substance tested.
8/ May be requested on a case-by-case basis.

TABLE A
GENERIC DATA REQUIREMENTS FOR TERBUFOS

Data Requirements	Composition 1/	Does EPA Have Data To Satisfy This Requirement? (Yes, No, or Partially)	Bibliographic Citation	Must Additional Data Be Submitted Under FIFRA Section 3(c)(2)(B)? 2/
§158.125 Residue Chemistry				
171-4 - Nature of Residue (Metabolism)				
- Plants	PAIRA	Yes 3/	00069512*; 00036123*; 00087689*; 00088210*; 00087688*; 00087692*; 00087686*; 00079429*; 00087691*; 00062871*	No
- Livestock	PAIRA and plant metabolites	Yes 3/	00087695*; 00032636*; 00036241*	No 4/
171-4 - Residue Analytical Method				
- Plant residues	Pure Analytical Standard and metabolites	Yes 3/	00036246*; 00032646*; 00042022*; 00036127*; 00079431*; 00062872*; 00042020*; 00088211*; 00049235*; 00087687*	No
- Animal residues	Pure Analytical Standard and metabolites	Yes 3/	00036242*; 00036241*; 00087702*; 00087704*;	No 4/
171-4 - Storage Stability Data	PAI	Yes	00042021*	No

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* Data submitted by American Cyanamid Company. These data may be compensable.

TABLE A
GENERIC DATA REQUIREMENTS FOR TERBUFOS

Data Requirements	Composition 1/	Does EPA Have Data To Satisfy This Requirement? (Yes, No, or Partially)	Bibliographic Citation	Must Additional Data Be Submitted Under FIFRA Section 3(c)(2)(B)?2/
§158.125 Residue Chemistry (continued)				
171-4 - Magnitude of the Residue-Residue Studies for Each Food Use				
° Sugar beets				
- Crop field trials				
° Sugar beet roots and tops	TEP	Yes	00036124*	No
- Processed Food/Feed				
° Sugar beet pulp	EP	Yes	00036129*	No
° Sugar beet sugar	EP	Yes 3/	00036129* 00036123*	No
°Corn				
- Crop field trials				
° Corn grain, forage, fodder	EP	Yes 3/	00087722*; 00042017*; 00042019*; 00039018*; GS0109001*	No
- Processed food/feed				
° Corn meal, corn oil	EP	No	-	No 5/

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* Data submitted by American Cyanamid Company. These data may be compensable.

TABLE A
GENERIC DATA REQUIREMENTS FOR TERBUFOS

Data Requirement	Composition 1/	Does EPA Have Data To Satisfy This Requirement? (Yes, No or Partially)	Bibliographic Citation	Must Additional Data Be Submitted Under FIFRA Section 3(c)(2)(B)? 2/
§158.125 Residue Chemistry (continued)				
171-4 - Magnitude of the Residue - Residue Studies (continued)				
° Sorghum				
- Crop field trials				
° Sorghum grain, forage, fodder	TEP	Yes	00079431*	No
- Processed Food/Feed				
° Sorghum flour and milled products	EP	No	-	No 5/
° Sorghum syrup	EP	No	-	No 6/
- Potable Water	EP	Not Applicable	-	-
- Fish	EP	Not Applicable	-	-
- Irrigated Crops	EP	Not Applicable	-	-
— Field trials	EP			
— Processed Food/Feed	EP			
- Food Handling	EP	Not Applicable	-	-
- Meat/milk/poultry/eggs	TGAI or plant metabolites	Yes 3/	00032636*; 00032641*; 00087702*	No 4/

*Data submitted by American Cyanamid. These data may be compensable.

TABLE A
GENERIC DATA REQUIREMENTS FOR TERBUFOS

§158.125 Residue Chemistry (continued)

1/ Composition: TGAI = Technical grade of the active ingredient; PAIRA = Pure active ingredient, radiolabelled; TEP = Typical end-use product; EP = End-use product.

2/ Data must be submitted no later than June, 1986 .

3/ All of the data cited are needed to satisfy this data requirement.

4/ These data are sufficient to support current established and pending crop tolerances, i.e., corn, sugar beets, sorghum, soybean, cabbage, broccoli, and cauliflower. Additional studies may be required to support new livestock feed crops.

5/ There is no reasonable expectation that detectable residues will be found.

6/ These data are not required to support the current established tolerance on grain sorghum (which does not include sweet sorghum).

TABLE A
GENERIC DATA REQUIREMENTS FOR TERBUFOS

Data Requirement	Composition 1/	Use Pattern 2/	Does EPA Have Data To Satisfy This Requirement? (Yes, No or Partially)	Bibliographic Citation	Must Additional Data Be Submitted Under FIFRA Section 3(c)(2)(B)? 3/
§158.130 Environmental Fate					
DEGRADATION STUDIES-LAB:					
161-1 - Hydrolysis	TGAI or PAIRA	A	Yes	00087694*	No
Photodegradation					
161-2 - In water	TGAI or PAIRA	A	Partial	00087694*	Yes 5/
161-3 - On soil	TGAI or PAIRA	-	No	-	No 6/
161-4 - In Air	TGAI or PAIRA	A	No	-	No 14/
METABOLISM STUDIES-LAB:					
162-1 - Aerobic Soil	TGAI or PAIRA	A	Yes	00087690*	No
162-2 - Anaerobic Soil	TGAI or PAIRA	A	Yes	00087690*	No
162-3 - Anaerobic Aquatic	TGAI or PAIRA	-	No	-	No 7/
162-4 - Aerobic Aquatic	TGAI or PAIRA	-	No	-	No 8/
MOBILITY STUDIES:					
163-1 - Leaching and Adsorption/Desorption	TGAI or PAIRA	A	Yes	00087693*	No
163-2 - Volatility (Lab)	TEP	A	No	-	Yes
163-3 - Volatility (Field)	TEP	A	No	-	Reserved 4/

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* Data submitted by American Cyanamid. These data may be compensable.

TABLE A
GENERIC DATA REQUIREMENTS FOR TERBUFOS

Data Requirement	Composition 1/	Use Pattern 2/	Does EPA Have Data To Satisfy This Requirement? (Yes, No or Partially)	Bibliographic Citation	Must Additional Data Be Submitted Under FIFRA Section 3(c)(2)(B)? 3/
§158.130 Environmental Fate (continued)					
DISSIPATION STUDIES-FIELD:					
164-1 - Soil	TEP	A	Yes 13/	00087708*; 00087706*	No
164-2 - Aquatic (Sediment)	TEP	-	No	-	No 8/
164-3 - Forestry	TEP	-	No	-	No 9/
164-4 - Combination and Tank Mixes		-	No	-	No 10/
164-5 - Soil, Long-term	TEP	-	No	-	No 11/
ACCUMULATION STUDIES:					
165-1 - Rotational Crops (Confined)	PAIRA	A	Yes	00087692*	No
165-2 - Rotational Crops (Field)	TEP	A	No	-	Yes
165-3 - Irrigated Crops	TEP	-	No	-	No 12/
165-4 - In Fish	TGAI or PAIRA	A	Yes	00085184*	No
165-5 - In Aquatic Non-Target Organisms	TEP	-	No	-	No 7/
MONITORING STUDIES					
- Soil, and water, sediment and fish	TEP	A	No	-	Yes 15/

* Data submitted by American Cyanamid. These data may be compensable.

TABLE A
GENERIC DATA REQUIREMENTS FOR TERBUFOS

§158.130 Environmental Fate (continued)

1/ Composition: TGAI = Technical grade of the active ingredient; PAIRA = Pure active ingredient, radiolabelled; TEP = Typical end-use product.

2/ The use patterns are coded as follows: A=Terrestrial, Food Crop; B=Terrestrial, Non-Food; C=Aquatic, Food Crop; D=Aquatic, Non-Food; E=Greenhouse, Food Crop; F=Greenhouse, Non-Food; G=Forestry; H=Domestic Outdoor; I=Indoor.

3/ Data must be submitted no later than June, 1986.

4/ Reserved pending result of lab volitility data (163-2).

5/ A study utilizing proper controls is needed.

6/ This study is not required to support the current application method of soil incorporation.

7/ This study is not required to support the current use pattern which does not include aquatic, forestry or aquatic impact uses.

8/ This study is not required to support the current use pattern which does not include aquatic or aquatic impact uses.

9/ This study is not requried to support the current use pattern which does not include forestry uses.

10/ There are no current registered combination or tank mixes for terbufos.

11/ This study is not required because less than 50% terbufos residues remain upon subsequent application.

12/ This study is not required to support the current use pattern which does not include aquatic uses.

13/ Both data citations are needed to satisfy this data requirement.

14/ This data is not required to support the current uses of terbufos which are outdoor, soil-incorporated uses.

15/ The objective of this monitoring requirement is to measure real world levels of terbufos and metabolites in treated fields and ponds adjacent to fields where terbufos is used.

The majority of terbufos marketed is used for corn rootworm control and it is most likely that environmental concerns will arise in the corn growing areas of the U.S. The application sites chosen should possess a known application history and be adjacent to ponds. Geographic areas for sampling should include: corn belt states, plains states and lake states.

Soil in treated fields should be monitored before and after application of terbufos. Pond water, sediment and fish should be monitored before and after fields are treated with terbufos. The scheme of monitoring (where, when, how) should reflect the attempt to measure maximum residues. Fish samples should be analyzed for cholinesterase inhibition, as well as terbufos residues. Baseline cholinesterase levels in fish brains should be established both in the ponds at the treatment sites and in an area without any history of anticholinesterase pesticide use (e.g., ponds near pastureland, but not where hay is harvested). The pH-stat technique as described by Coppage (1971) should be used. Metabolites as well as parent levels should be monitored (Cook, et. al., 1976). Additional information on this type of field study can be found in Tagatz, et.al. (1974) and Coppage and Braidech (1976).

Treatment rates should be at highest recommended rate for that site and crop. Normal agricultural practice should be followed, including repeated applications if appropriate. If possible, some sites with a history of terbufos treatment should also be chosen.

The monitoring protocol (including analytical methodology) must be submitted to the Agency, prior to initiating the study, with enough lead time for Agency review (two months).

TABLE A
GENERIC DATA REQUIREMENTS FOR TERBUFOS

Data Requirement	Composition 1/	Use Patterns 2/	Does EPA Have Data To Satisfy This Requirement? (Yes, No or Partially)	Bibliographic Citation 17/	Must Additional Data Be Submitted Under FIFRA Section 3(c)(2)(B)?3/
§158.135 Toxicology					
ACUTE TESTING:					
81-1 - Oral LD_{50} - Rat	TGAI	A	Yes 8/	00037467* 00037471* 00035121** 00029863**	No
81-2 - Dermal LD_{50}	TGAI	A	Partial	00037467*	Yes 4/
81-3 - Inhalation LC_{50} - Rat	TGAI	A	No	-	Yes
81-7 - Acute Delayed Neurotoxicity - Hen	TGAI	A	Yes 9/	00037472* 00045379*	No
SUBCHRONIC TESTING:					
82-1 - 90-Day Feeding - Rodent, Non-rodent	TGAI	A	Yes 10/	00109446* 00037469*	No
82-2 - 21-Day Dermal	TGAI	A	Yes	00085169*	No
82-3 - 90-Day Dermal	TGAI	A	No	-	No 5/
82-4 - 90-Day Inhalation - Rat	TGAI	A	No	-	No 6/
82-5 - 90-Day Neurotoxicity-Hen/Mammal	TGAI	A	No	-	No 7/

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* Data submitted by American Cyanamid. These data may be compensable.
** Data submitted by Aceto Chemical Co. These data may be compensable.

TABLE A
GENERIC DATA REQUIREMENTS FOR TERBUFOS

Data Requirement	Composition 1/	Use 2/ Pattern	Does EPA Have Data To Satisfy This Requirement? (Yes, No or Partially)?	Bibliographic Citation	Must Additional Data Be Submitted Under FIFRA Section 3(c)(2)(B)? 3/
§158.135 Toxicology (continued)					
CHRONIC TESTING:					
83-1 - Chronic Toxicity - 2 species: Rodent and Non-rodent					
- Rat	TGAI	A	Partial	00045378*; 00049236*	Yes 12/
- Dog	TGAI	A	Partial	00069502*; 00041139*	Yes 13/
83-2 - Oncogenicity Study - 2 species: Rat and Mouse preferred					
- Rat	TGAI	A	Partial	00049236*; 00045378*	Yes 12/
- Mouse	TGAI	A	Partial	00085170*; 00045380*	Yes 14/
83-3 - Teratogenicity - 2 species	TGAI	A	No	-	Yes
83-4 - Reproduction, 2-generation	TGAI	A	Yes 15/	00085172* 00037473*	No

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* Data submitted by American Cyanamid. These data may be compensable.

TABLE A
GENERIC DATA REQUIREMENTS FOR TERBUFOS

Data Requirement	Composition 1/	Use Pattern 2/	Does EPA Have Data To Satisfy This Requirement? (Yes, No or Partially)	Bibliographic Citation	Must Additional Data Be Submitted Under FIFRA Section 3(c)(2)(B)? 3/
§158.135 Toxicology (continued)					
MUTAGENICITY TESTING					
84-2 - Gene Mutation	TGAI	A	Partial	00063209*	Yes 11/
- In vitro mammalian cell point mutation L5178Y (TK); or CHO (HGPRT); or V79 (HGPRT).	TGAI	A	No	-	Yes
84-2 - Chromosomal Aberration	TGAI	A	No	-	Yes
- In vitro cytogenetic damage: both chromosomal aberration and SCE (in CHO cells; or human lymphocytes; or other rodent/human cell lines/strains.	TGAI	A	No	-	Yes
- In vivo cytogenetics test for chromosomal aberrations using bone marow preparations of rats.	TGAI	A	No	-	Yes
- Dominant lethal test in rats or mice.	TGAI	A	No	-	Yes
84-2 - Other Mechanisms of Mutagenicity	TGAI	A	Partial	00063209*	Yes 11/
- In vitro/in vivo primary hepatocyte repair for UDS testing both in vivo and in vitro exposure of cells to terbufos.	TGAI	A	No	-	Yes

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* Data submitted by American Cyanamid. These data may be compensable.

TABLE A
GENERIC DATA REQUIREMENTS FOR TERBUFOS

Data Requirement	Composition	Use 2/ Pattern	Does EPA Have Data To Satisfy This Requirement? (Yes, No or Partially)?	Bibliographic Citation	Must Additional Data Be Submitted Under FIFRA Section 3(c)(2)(B)? 3/
§158.135 Toxicology (continued)					
SPECIAL TESTING					
85-1 - General Metabolism	PAI or PAIRA	A	Yes	00087695*	No
85-2 - Domestic Animal Safety	Choice	A	No	-	No 16/

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*Data submitted by American Cyanamid. These data may be compensable.

TABLE A
GENERIC DATA REQUIREMENTS FOR TERBUFOS

§158.135 Toxicology (continued)

1/ Composition: TGAI = Technical grade of the active ingredient; PAI = Pure active ingredient; PAIRA = Pure active ingredient, radiolabelled; Choice = Choice of several test substances determined on a case-by-case basis.
2/ The use patterns are coded as follows: A=Terrestrial, Food Crop; B=Terrestrial, Non-Food; C=Aqautic, Food Crop; D=Aquatic, Non-Food; E=Greenhouse, Food Crop; F=Greenhouse, Non-Food; G=Forestry; H=Domestic Outdoor; I=Indoor.
3/ Data must be submitted no later than June, 1986.
4/ The acute dermal LD_{50} was performed on one sex; additional data must be submitted on the other sex, or a repeat study in rats (M + F) is required.
5/ The 21 day dermal study is adequate to assess the dermal exposure associated with the current pesticidal use of terbufos.
6/ This study is not required. It is unlikely that the current pesticidal use of terbufos will involve repeated inhalation exposure, i.e., as granular formulations applied as a soil incorporated treatment.
7/ This test is not required because the results of the acute delayed neurotoxicity test were negative.
8/ Data citations 00037467, and 00037471 combined, satisfy this data requirement for the technical currently registered under EPA Reg. No. 241-241. Data citation 00035121 satifies this data requirement for the technical currently pending under File Symbol 2749-UEL. These data citations may not be adequate to satisfy this requirement for technicals which differ from those described herein.
9/ Both data citations are needed to satisfy this data requirement.
10/ Data citation number 00109446 is sufficient to satisfy this data requirement.
11/ Additional tests as specified in TABLE A are required.
12/ The submitted 2-year rat study lacked microscopic examinations on animals that died or were sacrificed moribund during the study: or for the 3-month interim sacrifice.
13/ The submitted 6-month dog study was not adequate because the actual dosages could not be determined. A one year study is now required.
14/ The submitted 18-month mouse study lacks a sufficient number of histologically examined animals per sex per group.
15/ Both data citations are needed to satisfy this data requirement.
16/ Testing is not required based on current registered uses. However, depending on the extent of future use in feed items and whether or not tolerances would be requested in meat and milk, a combined study can be performed for both residues and domestic animal safety determinations.
17/ Except as noted in footnote 8, these data citations pertain to the technical currently registered under EPA Reg. No. 241-241, and may not be applicable to technicals which differ from that described herein.

TABLE A
GENERIC DATA REQUIREMENTS FOR TERBUFOS

Data Requirement	Composition 1/	Pattern 2/	Does EPA Have Data To Satisfy This Requirement? (Yes, No or Partially)	Bibliographic Citation	Must Additional Data Be Submitted Under FIFRA Section 3(c)(2)(B)?
§158.140 Reentry Protection					
132-1 - Foliar Dissipation	TEP	A	No		No 3/
132-1 - Soil Dissipation	TEP	A	No		No 3/
133-3 - Dermal Exposure	TEP	A	No		No 3/
133-4 - Inhalation Exposure	TEP	A	No		No 3/

1/ Composition: TEP = Typical end-use product.
2/ The use patterns are coded as follows: A=Terrestrial, Food Crop; B=Terrestrial, Non-Food; C=Aquatic, Food Crop; D=Aquatic, Non-Food; E=Greenhouse, Food Crop; F=Greenhouse, Non-Food; G=Forestry, H=Domestic Outdoor; I=Indoor.
3/ There is little potential for worker exposure based on the composition of the present registered TEP which is a granular formulation and since the present registered uses require soil incorporation of the granules.

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* Data submitted by American Cyanamid. These data may be compensable.

TABLE A
GENERIC DATA REQUIREMENTS FOR TERBUFOS

Data Requirement	Composition 1/	Use 2/ Pattern	Does EPA Have Data To Satisfy This Requirement? (Yes, No or Partially)	Bibliographic Citation	Must Additional Data Be Submitted Under FIFRA Section 3(c)(2)(B)?3/
§158.145 Wildlife and Aquatic Organisms					
AVIAN AND MAMMALIAN TESTING					
71-1 - Avian Oral LD_{50}	TGAI	A	Yes	00106551*	No
71-2 - Avian Dietary LC_{50}	TGAI	A	Yes 8/	00087717** 00035120**	No
71-3 - Wild Mammal Toxicity	TGAI	A	Not Applicable	-	-
71-4 - Avian Reproduction	TGAI	A	Partial	00085177* 00097892*	Yes 5/
71-5 - Simulated and Actual Field Testing - Mammals and Birds	TEP	A	Partial	00085178* 00087726* 00085180* 00085179* 00085183*	Yes 6/
AQUATIC ORGANISM TESTING					
72-1 - Freshwater Fish LC_{50}	TGAI	A	Yes 9/	00037483* 00085176* 00087718**	No
	TEP	A	Yes	GS0109002 GS0109003	No

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* Data submitted by American Cyanamid. These data may be compensable.

** Data submitted by Aceto Chemical Co., Inc. These data may be compensable.

TABLE A
GENERIC DATA REQUIREMENTS FOR TERBUFOS

Data Requirement	Composition 1/	Use Pattern 2/	Does EPA Have Data To Satisfy This Requirement? (Yes, No or Partially)	Bibliographic Citation	Must Additional Data Be Submitted Under FIFRA Section 3(c)(2)(B)? 3/
§158.145 Wildlife and Aquatic Organisms (continued)					
72-2 - Acute LC_{50} Freshwater Invertebrates	TGAI	A	Yes 7/	00101495* 00085176*	No
-do-	TEP	A	Yes	GS0109004	No
72-3 - Acute LC_{50} Estuarine and Marine Organisms	TGAI	A 4/	No	-	Yes
72-4 - Fish Early Life Stage and Aquatic Invertebrate Life-Cycle	TGAI	A	No	-	Yes 11/
72-5 - Fish - Life-Cycle	TGAI	A	Reserved 10/		
72-6 - Aquatic Organism Accumulation	TGAI, PAI or Degradation Product	A	Reserved 10/		
72-7 - Simulated or Actual Field Testing - Aquatic Organisms	TEP	A	Reserved 10/		

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* Data submitted by American Cyanamid. These data may be compensable.

TABLE A
GENERIC DATA REQUIREMENTS FOR TERBUFOS

§158.145 Wildlife and Aquatic Organisms
(continued)

1/ Composition: TGAI = Technical grade of the active ingredient; PAI = pure active ingredient; TEP = Typical end-use product;

2/ The use patterns are coded as follows: A=Terrestrial, Food Crop; B=Terrestrial, Non-Food Crop; C=Aquatic, Food Crop; D=Aquatic, Non-Food; E=Greenhouse, Food Crop; F=Greenhouse, Non-Food; G=Forestry; H=Domestic Outdoor; I=Indoor.

3/ Data must be submitted no later than June, 1986.

4/ This data is necessary to support corn and sorghum uses.

5/ All pen-by-pen data must be provided to enable full statistical evaluation of results.

6/ Actual field testing should be conducted with the corn use, using the present maximum application rate (2.4 oz a.i./1000 feet of row). Census data should be taken before and after treatment, intensive searches for dead or dying animals should be made within one day of application, and analyses for cholinesterase inhibition should be conducted. A protocol for conducting this study should be submitted to the Agency for review, at least six months prior to initiation of testing.

7/ The data citation 00101495 is sufficient to satisfy this data requirement.

8/ Data citation 00087717 is sufficient to satisfy the data requirement for a Bobwhite quail dietary LC_{50} study. Though data citation 00035120 only partially satisfies the guideline requirement for a mallard duck dietary LC_{50} study, further mallard testing is not deemed warranted because of the food rejection problem.

9/ To satisfy this data requirement, both a coldwater species and a warmwater species study must be cited. Either data citation 00087718, or 00037483 is sufficient to satisfy the data required for a coldwater species; and either 00087718 or 00037483 is sufficient to satisfy the data requirement for a warmwater species.

10/ The need for these studies is reserved pending evaluation of: 1) the monitoring data (§ 158.130), 2) completion of additional EECs (discussed in Chapter II), 3) the outstanding aquatic studies (72-3 and 72-4). This information will then dictate the need for anyone of the reserved studies.

11/ The applicant should consult with the Agency regarding the appropriate test species and test methodologies.

TABLE A
GENERIC DATA REQUIREMENTS FOR TERBUFOS

Data Requirements	Composition 1/	Use Pattern 2/	Does EPA Have Data To Satisfy This Requirement? (Yes, No or Partially)	Bibliographic Citation	Must Additional Data Be Submitted Under FIFRA Section 3(c)(2)(B)?
§158.150 Plant Protection					
121-1 - TARGET AREA PHYTOTOXICITY	EP				
NONTARGET AREA PHYTOTOXICITY					
TIER I					
122-1 - Seed Germination/ Seedling Emergence	TGAI				
122-1 - Vegetative Vigor	TGAI		THESE REQUIREMENTS ARE GENERALLY WAIVED UNLESS IT IS BELIEVED THERE IS A PHYTOTOXICITY PROBLEM		
122-2 - Aquatic Plant Growth	TGAI				
TIER II					
123-1 - Seed Germination/ Seedling Emergence	TGAI				
123-1 - Vegetative Vigor	TGAI				
123-2 - Aquatic Plant Growth	TGAI				
TIER III					
124-1 - Terrestrial Field	TEP				
124-2 - Aquatic Field	TEP				

1/ Composition: TGAI = Technical grade of the active ingredient; TEP = Typical end-use product. EP = End-use product.

2/ The use patterns are coded as follows: A=Terrestrial, Food Crop; B=Terrestrial, Non-Food Crop; C=Aquatic, Food Crop; D=Aquatic, Non-Food; E=Greenhouse, Food Crop; F=Greenhouse, Non-Food; G=Forestry; H=Domestic Outdoor; I=Indoor.

TABLE A
GENERIC DATA REQUIREMENTS FOR TERBUFOS

Data Requirement	Composition 1/	Use 2/ Pattern	Does EPA Have Data To Satisfy This Requirement? (Yes, No or Partially)	Bibliographic Citation	Must Additional Data Be Submitted Under FIFRA Section 3(c)(2)(B)?
§158.155 Nontarget Insect					
NONTARGET INSECT TESTING - POLLINATORS:					
141-1 - Honey bee acute contact LD_{50}	TGAI	A	Yes	00066220*	No
141-2 - Honey bee - toxicity of residues on foliage	TEP	A	No	-	No 3/
141-3 - Wild bees important in alfalfa pollination - toxicity of residues on foliage	TEP	A	No	-	No 4/
141-4 - Honey bee subacute feeding study	(Reserved)	A	Reserved 5/		
141-5 - Field testing for pollinators	TEP	A	No	-	No 3/

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* Data submitted by Penick Corporation. These data may be compensable.

TABLE A
GENERIC DATA REQUIREMENTS FOR TERBUFOS

Data Requirement	Composition [1]	Use Pattern [2]	Does EPA Have Data To Satisfy This Requirement? (Yes, No or Partially)	Bibliographic Citation	Must Additional Data Be Submitted Under FIFRA Section 3(c)(2)(B)?
§158.155 Nontarget Insect (continued)					
NONTARGET INSECT TESTING - AQUATIC INSECTS:					
142-1 - Acute toxicity to aquatic insects	(Reserved) [6]				
142-2 - Aquatic insect life-cycle study	(Reserved) [6]				
142-3 - Simulated or actual field testing for aquatic insects	(Reserved) [6]				
143-1 thru 143-3 - NONTARGET INSECT TESTING-PREDATORS AND PARASITES	(Reserved) [6]				

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[1] Composition: TGAI = Technical grade of the active ingredient; TEP = Typical end-use product.

[2] The use patterns are coded as follows: A=Terrestrial, Food Crop; B=Terrestrial, Non-Food; C=Aquatic, Food Crop: D=Aqautic, Non-Food; E=Greenhouse, Food Crop; F=Greenhouse, Non-Food; G=Forestry; H=Domestic Outdoor; I=Indoor.

[3] Since the current registered uses of terbufos will not result in bee exposure, honey bee testing beyond the first level (acute contact LD_{50}) is not required.

[4] This data is not required to support the current registered terbufos products which are not intended for use as a foliar application to seed alfalfa.

[5] Reserved pending development of test methodology. Also refer to footnote [3].

[6] Reserved pending decision as to whether the data requirement should be established.

TABLE B
PRODUCT SPECIFIC DATA REQUIREMENTS FOR MANUFACTURING-USE PRODUCTS CONTAINING TERBUFOS

Data Requirement	Composition 1/	Does EPA Have Data To Satisfy This Requirement? (Yes, No or Partially)	Bibliographic 7/ Citation	Must Additional Data Be Submitted Under FIFRA Section 3(c)(2)(B)? 2/
§158.120 Product Chemistry				
Product Identity				
61-1 - Identity of Ingredients	MP	Yes	00040385*	No
61-2 - Statement of Composition	MP	Partial	00085161*	Yes 3/
61-3 - Discussion of Formation of Ingredients	MP	Yes	00069499* 6/ 00085160* 6/ 00087711* 6/	No
Analysis and Certification of Product Ingredients:				
62-1 - Preliminary Analysis	MP	Yes	00040389*	No
62-2 - Certification of Limits	MP	Partial	00087711* 00085160*	Yes 4/
62-3 - Analytical Methods for Enforcement of Limits	MP	Partial	00040388* 00087712* 00040390*	Yes 5/
Physical and Chemical Characteristics				
63-2 - Color	MP	Yes	00040385*	No
63-3 - Physical State	MP	Yes	00040385*	No
63-4 - Odor	MP	Yes	00040385*	No
63-7 - Density, bulk density, or specific gravity	MP	Yes	00040385*	No

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*Data submitted by American Cyanamid. These data may be compensable.

TABLE B
PRODUCT SPECIFIC DATA REQUIREMENTS FOR MANUFACTURING-USE PRODUCTS CONTAINING TERBUFOS

Data Requirement	Composition 1/	Does EPA Have Data To Satisfy This Requirement? (Yes, No or Partially)	Bibliographic Citation	Must Additional Data Be Submitted Under FIFRA Section 3(c)(2)(B)? 2/
§158.120 Product Chemistry (continued)				
63-12 - pH	MP	No	-	Yes
63-14 - Oxidizing or reducing action	MP	No	-	Yes
63-15 - Flammability	MP (Combustible liquids only)	No	-	Yes
63-16 - Explodability	MP	No	-	Yes
63-17 - Storage Stability	MP	No	-	Yes
63-18 - Viscosity	MP (Liquids only)	No	-	Yes
63-19 - Miscibility	MP (Emulsifiable liquids only)	No	-	Yes
63-20 - Corrosion	MP	No	-	Yes
Other Requirements				
64- 1 - Submittal of Samples	Choice	-	-	No 8/

TABLE B
PRODUCT SPECIFIC DATA REQUIREMENTS FOR MANUFACTURING-USE PRODUCTS CONTAINING TERBUFOS

§158.120 Product Chemistry (continued)

1/ Composition: MP = Manufacturing-use product; Choice = Choice of several test substances determined on a case-by-case basis.
2/ Data must be submitted no later than December 1983.
3/ Further information is needed on the composition of starting materials.
4/ A declaration and certification of limits is required.
5/ Validation data for the analytical methods are required.
6/ Any one of these data citations are adequate to meet this data requirement.
7/ These data citations pertain to the MP currently registered under EPA Reg. No. 241-241 and may not be applicable to MPs which differ from that described herein.
8/ May be required on a case-by-case basis.

TABLE B

PRODUCT SPECIFIC DATA REQUIREMENTS FOR MANUFACTURING-USE PRODUCTS CONTAINING TERBUFOS

Data Requirement	Composition 1/	Does EPA Have Data To Satisfy This Requirement? (Yes, No or Partially)	Bibliographic Citation 6/	Must Additional Data Be Submitted Under FIFRA Section 3(c)(2)(B)? 2/
§158.135 Toxicology				
ACUTE TESTING				
81-1 - Oral LD_{50} - Rat	MP	Yes 5/	00037467* 00037471* 00035121** 00029863**	No
81-2 - Dermal LD_{50}	MP	Partial	00037467*	Yes 4/
81-3 - Inhalation LC_{50} - Rat	MP	No	-	Yes
81-4 - Primary Eye Irritation - Rabbit	MP	Yes	00044957*	No
81-5 - Primary Dermal Irritation	MP	Yes	00044957*	No
81-6 - Dermal Sensitization	MP	No	-	No 3/

1/ Composition: MP = Manufacturing-use product.

2/ Data must be submitted no later than December 1983.

3/ This data requirement is waived because mortality would occur before sensitization.

4/ This data requirement for testing in male rabbits is satisfied. Acute dermal LD_{50} data for female rabbits must be submitted.

5/ Data citations 00037467, and 00037471 combined, satisfy this data requirement for the manufacturing use product (MP) currently registered under EPA Reg. No. 241-241. Data citation 00035121 satisfies ths data requirement for the MP currently pending under File Symbol 2749-UEL. These data citations may not be adequate to satisfy this requirement for MPs which differ from those described herein.

6/ Except as noted in footnote 5, these data citations pertain to the manufacturing use product (MP) currently registered under EPA Reg. No. 241-241, and may not be applicable to MPs which differ from that described herein.

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* Data submitted by American Cyanamid. These data may be compensable.

** Data submitted by Aceto Chemical Co. These data may be compensable.

IV. REQUIREMENT FOR SUBMISSION OF PRODUCT-SPECIFIC DATA

Note: This section applies only to manufacturing-use products, not end-use products.

A necessary first step in determining which statements must appear on your product's label is the completion and submission to EPA of product-specific data* listed on the form entitled "Product Specific Data Report" (EPA Form 8580-4, Appendix IV-1) to fill "gaps" identified by EPA concerning your product. Under the authority of FIFRA Section 3(c)(2)(B), EPA has determined that you must submit these data to EPA in order to register or reregister your product(s). All of these data must be submitted not later than six months after you receive this guidance document.

"Product-Specific Data Requirements for Manufacturing-Use Products" appearing in Table B permit you to determine which product-specific data you must submit. This can be done by examining the entries in the column of those tables entitled "Must Data Be Submitted Under §3(c)(2)(B)."

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*/ Product specific data pertains to data that support the formulation which is marketed; it usually includes product chemistry data and acute toxicology data.

V. SUBMISSION OF REVISED LABELING AND PACKAGING INFORMATION

Note: This section applies only to manufacturing-use products, not end-use products.

The Agency requires applicants for registration or reregistration to ensure that each label (1) contains accurate, complete, and sufficient instructions and precautions, reflecting the results of data concerning the product and its ingredients, and (2) incorporates labeling format and terminology which are sufficiently standardized to avoid user confusion.

As part of your application, you will be required to submit draft labeling consistent with: applicable product-specific data; the precautionary statements and use directions; and the regulations concerning classification [40 CFR §162.11(c)], packaging [40 CFR §162.16], and labeling [40 CFR §162.10, Appendix V-1 and V-2], as indicated by the following paragraphs of this section of the guidance document.

You will be informed later when you must submit the revised labeling set forth in this guidance package.

A. Label Contents

40 CFR §162.10 (Appendix V-1) requires that certain specific labeling statements must appear at certain locations on the label. This is referred to as format labeling. Specific label items listed below are keyed to Tables D, E, and F (Appendix VI-2).

Item 1. PRODUCT NAME - The name, brand, or trademark is required to be located on the front panel, preferably centered in the upper part of the panel. The name of a product will not be accepted if it is false or misleading. See Appendix V-1. [40 CFR §162.10(b)]

Item 2. COMPANY NAME AND ADDRESS - The name and address of the registrant or distributor is required on the label. The name and address should preferably be located at the bottom of the front panel or at the end of the label text. See Appendix V-1. [40 CFR §162.10(c)]

Item 3. NET CONTENTS - A net content statement is required on all labels. The preferred location is the bottom of the front panel immediately above the company name and address, or at the end of the label text. The net contents must be stated in terms of weight, expressed as avoirdupois pounds and ounces, and stated in terms of the largest suitable unit, i.e., "1 pound 10 ounces" rather than "26 ounces." In addition to the required units specified, net contents may be expressed in metric units. See Appendix V-1. [40 CFR §162.10(d)]

Item 4. EPA REGISTRATION NUMBER - The registration number assigned to the pesticide product must appear on the label, preceded by the phrase "EPA Registration No.," or "EPA Reg. No." The registration number must be set in type of a size and style similar to other print on that part of the label on which it appears and must run parallel to it. The registration number and the required identifying phrase must not appear in such a manner as to suggest or imply recommendation or endorsement of the product by the Agency. See Appendix V-1. [40 CFR §162.10(e)]

Item 5. EPA ESTABLISHMENT NUMBER - The EPA establishment number, preceded by the phrase "EPA Est." is the final establishment at which the product was produced, and may appear in any suitable location on the label or immediate container. It must also appear on the wrapper or outside container of the package if the EPA establishment registration number on the immediate container cannot be clearly read through such wrapper or container. See Appendix V-1. [40 CFR §162.10(f)]

Item 6. INGREDIENT STATEMENT - An ingredient statement is required on the front panel and must contain the name and percentage by weight of each active ingredient and the total percentage by weight of all inert ingredients. The preferred location is immediately below the product name. The ingredient statement must run parallel with, and be clearly distinguished from, other text on the panel. It must not be placed in the body of other text. See Appendix V-1. [40 CFR 162.10(g)]

Item 6A. POUNDS PER GALLON STATEMENT - For liquid agricultural formulations, the pounds per gallon of active ingredient must be indicated on the label.

Item 7. FRONT LABEL PRECAUTIONARY STATEMENTS - All labels are required to have precautionary statements grouped together on the front panel, preferably within a block outline. The table below shows the minimum type size requirements on various size labels, as set forth in the Regulations.

Size of Label on Front Panel in Square Inches	Signal Word as Required Minimum Type Size All Capitals	"Keep Out of Reach of Children" as Required
5 and under	6 point	6 point
above 5 to 10	10 point	6 point
above 10 to 15	12 point	8 point
above 15 to 30	14 point	10 point
over 30	18 point	12 point

Item 7A. CHILD HAZARD WARNING STATEMENT - All labels are required to have the statement "Keep Out of Reach of Children" located on the front panel above the signal word except where contact with children during distribution or use is unlikely. See Appendix V-1. [40 CFR §162.10(h)(1)(ii)]

Item 7B. SIGNAL WORD - The signal word (Caution, Warning, or Danger) is required on the front panel immediately below the child hazard warning statement. See Appendix V-1. [40 CFR §162.10 (h)(1)(i)]

Item 7C. SKULL & CROSSBONES AND WORD "POISON" - On products assigned a toxicity Category I on the basis of oral, inhalation, or dermal toxicity, the word "Poison" shall appear on the label in red on a background of distinctly contrasting color and the skull and crossbones shall appear in immediate proximity to the word poison. See Appendix V-1. [40 CFR §162.10(h)(1)(i)]

Item 7D. STATEMENT OF PRACTICAL TREATMENT - A statement of practical treatment (first aid or other) shall appear on the label of pesticide products in toxicity Categories I, II, and III. See Appendix V-1. [40 CFR §162.10(h)(1)(iii)]

Item 7E. REFERRAL STATEMENT - The statement "See Side (or Back) Panel for Additional Precautionary Statements" is required on the front panel for all products, unless all required precautionary statements appear on the front panel. See Appendix V-1. [40 CFR §162.10(h)(1)(iii)]

Item 8. SIDE/BACK PANEL PRECAUTIONARY LABELING - The precautionary statements as listed below must appear together on the label under the heading "PRECAUTIONARY STATEMENTS." The preferred location is at the top of the side or back panel preceding the directions for use, and it is preferred that these statements be surrounded by a block outline. Each of the three hazard warning statements must be headed by the appropriate hazard title. See Appendix V-1. [40 CFR §162.10 (h)(2)]

Item 8A. HAZARD TO HUMANS AND DOMESTIC ANIMALS - Where a hazard exists to humans or domestic animals, precautionary statements are required indicating the particular hazard, the route(s) of exposure and the precautions taken to avoid accident, injury or damage. See Appendix V-1. [40 CFR §162.10 (h)(2)(i)]

Item 8B. ENVIRONMENTAL HAZARD - Where a hazard exists to non-target organisms excluding humans and domestic animals, precautionary statements are required stating the nature of the hazard and the appropriate precautions to avoid potential accident, injury, or damage. See Appendix V-1. [40 CFR §162.10(h)(2)(ii)]

Item 8C. PHYSICAL OR CHEMICAL HAZARD

1. Flammability statement. Precautionary statements relating to flammability of a product are required to appear on the label if it meets the criteria in Appendix V-3. The requirement is based on the results of the flashpoint determinations and flame extension tests required to be submitted for all products. These statements are to be located in the side/back panel precautionary statements section, preceded by the heading "Physical/Chemical Hazards." Note that no signal word is used in conjunction with the flammability statements.

2. Criteria for declaration of non-flammability. The following criteria will be used to determine if a product is non-flammable:

    a. A "non-flammable gas" is a gas (or mixture of gases) that will not ignite when a lighted match is placed against the open cylinder valve.

    b. A "non-flammable liquid" is one having a flashpoint greater than 350°F (177°C) as determined by the method specified in 40 CFR §163.61-8(c)(13)(ii) of Subpart D.

    c. A "non-flammable aerosol" is one which meets the following criteria:

        i. The flame extension is zero inches, using the method specified in 40 CFR §163.61-8(c)(13)(ii);

        ii. There is no flash back; and

        iii. The flashpoint of the non-volatile liquid component is greater than 350°F (177°C), determined by the method specified in 40 CFR §163.61-8(c)(13)(i).

3. Declaration of non-flammability. Products which meet the criteria for non-flammability specified above may bear the notation "non-flammable" or "nonflammable (gas, liquid, etc.)" on the label.

   It may appear as a substatement to the ingredients statement, or on a back or side panel, but shall not be highlighted or emphasized (as with an inordinately large type size) in any way that may detract from precaution.

4. Other physical/chemical hazard statements. When chemistry data submitted in accordance with 40 CFR §163.61-10(c) demonstrate hazards of a physical or chemical nature other than flammability, appropriate statements of hazard will be prescribed. Such statements may address hazards of explosivity, oxidizing or reducing capability, or mixing with other substances to produce toxic fumes.

Item 9. MISUSE STATEMENT - The following statement is required on your label: "It is a violation of Federal law to use this product in a manner inconsistent with its labeling." See Appendix V-1. [40 CFR §162.10(1)(2)(ii)]

Item 10A. STORAGE AND DISPOSAL BLOCK - All labels are required to bear storage and disposal statements. These statements are developed for specific containers, sizes, and chemical content. Make certain that the statement you use pertains specifically to your product. These instructions must be grouped and appear under the heading "Storage and Disposal" in the directions for use. This heading must be set in the same type sizes as required for the child hazard warning. Refer to Appendix V-5 for the latest specific storage and disposal product label statements.

Item 10B. DIRECTIONS FOR USE - Directions for use must be stated in terms which can be easily read and understood by the average person likely to use or to supervise the use of the pesticide. When followed, directions must be adequate to protect the public from fraud and from personal injury and to prevent unreasonable adverse effects on the environment. See Appendix V-1. [40 CFR §162.10]

B. Collateral Information

Bulletins, leaflets, circulars, brochures, data sheets, flyers, and other graphic printed matter which is referred to on the label or which is to accompany the product are termed collateral labeling. Such labeling may not bear claims or representations that differ in substance from those accepted in connection with registration of the product. It should be made part of the response to this notice and submitted for review.

VI. INSTRUCTIONS FOR SUBMISSION

All applications prepared in response to this Notice should be addressed as follows:

Mr. William H. Miller, Product Manager
Registration Division (TS-767)
Office of Pesticide Programs
Environmental Protection Agency
Washington, D.C. 20460
Phone No. (703) 557-2600

A. For each manufacturing-use product for which continued registration is desired:

1. Within 90 days from receipt of this document, you must submit the "FIFRA Section 3(c)(2)(B) Summary Sheet" EPA Form 8580-1. Refer to Appendix III-2 with appropriate attachments.

2. Within 6 months from receipt of this document registrants must submit:

   a. Confidential Statement of Formula, EPA Form 8570-4.

   b. Product Specific Data Report, EPA Form 8580-4 (Appendix IV-1).

   c. Two copies of any required product-specific data.

3. Within the time set forth in Table A, all generic data must be submitted by the affected registrant(s).

Note: If for any reason any required test is delayed or aborted so that meeting the agreed submission time will be delayed, notify the Product Manager listed above.

B. For each affected product for which continued registration is desired, within 90 days from receipt of this document submit the "FIFRA Section 3(c)(2)(B) Summary Sheet" (EPA Form 8580-1, Appendix III-2) with appropriate attachments.

C. You will be informed at a later date when you must submit your Application for Amended Pesticide Registration (EPA Form 8570-1) and the revised labeling set forth in this guidance package.

Guide to Use of This Bibliography

1. CONTENT OF BIBLIOGRAPHY. This bibliography contains citations of all studies considered relevant by EPA in arriving at the positions and conclusions stated elsewhere in the Standard. Primary sources for studies in this bibliography have been the body of data submitted to EPA and its predecessor agencies in support of past regulatory decisions. Selections from other sources including the published literature, in those instances where they have been considered, will be included.

2. UNITS OF ENTRY. The unit of entry in this bibliography is called a "study." In the case of published materials, this corresponds closely to an article. In the case of unpublished materials submitted to the Agency, the Agency has sought to identify documents at a level parallel to the published article from within the typically larger volumes in which they were submitted. The resulting "studies" generally have a distinct title (or at least a single subject), can stand alone for purposes of review, and can be described with a conventional bibliographic citation. The Agency has attempted also to unite basic documents and commentaries upon them, treating them as a single study.

3. IDENTIFICATION OF ENTRIES. The entries in this bibliography are sorted numerically by "Master Record Identifier," or MRID, number. This number is unique to the citation, and should be used at any time specific reference is required. It is not related to the six-digit "Accession Number" which has been used to identify volumes of submitted studies; see paragraph 4(d)(4) below for a further explanation. In a few cases, entries added to the bibliography late in the review may be preceded by a nine-character temporary identifier. These entries are listed after all MRID entries. This temporary identifier number is also to be used whenever specific reference is needed.

4. FORM OF ENTRY. In addition to the Master Record Identifier (MRID), each entry consists of a citation containing standard elements followed, in the case of material submitted to EPA, by a description of the earliest known submission. Bibliographic conventions used reflect the standards of the American National Standards Institute (ANSI), expanded to provide for certain special needs.

   a. Author. Whenever the Agency could confidently identify one, the Agency has chosen to show a personal author.

as author. As a last resort, the Agency has shown the first submitter as author.

b. Document Date. When the date appears as four digits with no question marks, the Agency took it directly from the document. When a four-digit date is followed by a question mark, the bibliographer deduced the date from evidence in the document. When the date appears as (19??), the Agency was unable to determine or estimate the date of the document.

c. Title. In some cases, it has been necessary for Agency bibliographers to create or enhance a document title. Any such editorial insertions are contained between square brackets.

d. Trailing Parentheses. For studies submitted to the Agency in the past, the trailing parentheses include (in addition to any self-explanatory text) the following elements describing the earliest known submission:

  (1) Submission Date. The date of the earliest known submission appears immediately following the word "received."

  (2) Administrative Number. The next element, immediately following the word "under," is the registration number, experimental use permit number, petition number, or other administrative number associated with the earliest known submission.

  (3) Submitter. The third element is the submitter, following the phrase "submitted by." When authorship is defaulted to the submitter, this element is omitted.

  (4) Volume Identification (Accession Numbers). The final element in the trailing parentheses identifies the EPA accession number of the volume in which the original submission of the study appears. The six-digit accession number follows the symbol "CDL," standing for "Company Data Library." This accession number is in turn followed by an alphabetic suffix which shows the relative position of the study within the volume. For example, within accession number 123456, the first study would be 123456-A; the second, 123456-B; the 26th, 123456-Z; and the 27th, 123456-AA.

OFFICE OF PESTICIDE PROGRAMS
REGISTRATION STANDARD BIBLIOGRAPHY
Citations Considered to be Part of the Data Base Supporting Registration Under the Standard

00029863 Consultox Laboratories (1975) Acute Oral and Percutaneous Toxicity Evaluations. (Unpublished study received Feb 3, 1976 under 2749-425; submitted by Aceto Chemical Co., Inc., Flushing, N.Y.; CDL:241780-A)

00032636 Fischer, J.E. (1979) Toxicity Data Report: Report No. A79-109. (Unpublished study received Jun 11, 1980 under 241-260; submitted by American Cyanamid Co., Princeton, N.J.; CDL:099451-B)

00032646 Palochak, M.E.; Shapiro, R.L. (1971) Microbiology Laboratory Report: Report No. 710903M1. (Unpublished study received Jan 19, 1971 under 52-127; prepared in cooperation with Hudson Laboratories, Inc., submitted by West Chemical Products, Inc., Lynbrook, N.Y.; CDL:000053-A)

00035120 Krize, J.W.; Terrel Y. (1978) Report: Avian Dietary LC_{50} (5-Day Dietary Exposure) of Enlist Technical (Terbufos Technical) EPA File Symbol 2749-UEL to Mallard Duck; Laboratory No. 8E-3451. (Unpublished study received Mar 27, 1979 under 2749-425; prepared by Cannon Laboratories, Inc., submitted by Aceto Chemical Co., Inc., Flushing, N.Y.; CDL:241730-A)

00035121 Parke, G.S.E.; Terrell, Y. (1976) Acute Oral Toxicity in Rats: Compound: Enlist Technical Insecticide (Terbufos) EPA File Symbol 2749-UEL: Laboratory No. 6E-3164. (Unpublished study received Nov 29, 1976 under 2749-425; prepared by Cannon Laboratories, Inc., submitted by Aceto Chemical Co., Inc., Flushing, N.Y.; CDL:241733-A)

00036123 Caballa, S.H.; Ku, C.; Miller, P.; et al. (1975) Summary—Metabolism of Counter (CL 92,100) in Sugar Beets. (Unpublished study including project no. 2-404 and report nos. C-698 and M-606, received Jun 10, 1975 under 5F1640; submitted by America Cyanamid Co., Princeton, N.J.; CDL:094445-G)

00036124 Higham, J.W.; Alvarez, C.G.; Burhardt, C.C.; et al. (1975) General Summary: Counter"(R) 15G Soil Insecticide Residues in Sugar Beet Tops and Roots. (Unpublished study received Jun 10, 1975 under 5F1640; submitted by American Cyanamid Co., Princeton, N.J.; CDL:094445-H)

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00036127 Higham, J.W.; Peterson, R.P. (1974) CL 92,100 and 92,100 Related Compounds: Gas Chromatographic Procedure for the Determination of CL 92,100 in Sugar Beet Tops (Greens) and Roots. Includes method M-395 dated Mar 1, 1973. (Unpublished study including report no. C-532, received Jun 10, 1975 under 5F1640; submitted by American Cyanamid Co., Princeton, N.J.; CDL:094445-K)

00036129 Peterson, R.P.; McGinnis, R.A. (1975) Counter (CL 92,100): Total Counter-Related Residues in Sugar Beet Dried Pulp and Juice (Thick and Thin): Report No. C-679. Includes method no. M-501 dated May 1, 1975. (Unpublished study received Jun 10, 1975 under 5F1640; prepared in cooperation with Spreckels Sugar co., submitted by American Cyanamid Co., Princeton, N.J.; CDL:094445-M.

00036234 American Cyanamid Company (19??) Name, Chemical Identity and Composition of AC 92,100. (Unpublished study received Apr 9, 1973 under 3G1340; CDL:093581-A)

00036241 Manuel, A.J. (1972) Total CL 92,100 and Its Metabolites in Milk: Report No. C-336. Includes method M-353 dated Jul 31, 1972. (Unpublished study received Apr 9, 1973 under 3G1340; submitted by American Cyanamid Co., Princeton, N.J; CDL:093581-J)

00036242 Manuel, A.J.; Peterson, R.P.; Potts, C.R.; et al. (1972) CL 92,100 and Its Metabolites in Cattle Fat, Muscle, Liver and Kidney: Report No. C-337. Includes method M-372 dated Nov 9, 1972. (Unpublished study received Apr 9, 1973 under 3G1340; submitted by American Cyanamid Co., Princeton, N.J.; CDL:093581-K)

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00037467 American Cyanamid Company (1972) Toxicity Data: O,O-Diethyl-S (tert-butylthiomethyl) phosphorodithioate Technical, 85.8% AC 2162-42: Report A-72-95. (Unpublished study received Apr 9, 1973 under 3G1340; CDL:093584-B)

00037469 Sabol, R.J.; Smith, J.M.; Wilson, N.H.; et al. (1972) A 3 and 24 Month Oral Toxicity and Carcinogenicity Study of AC 92, 100 in Rats: Three Month Report: Project No. 71R-725. (Unpublished study received Apr 9, 1973 under 3G1340; prepared by Bio/dynamics, Inc., submitted by American Cyanamid Co., Princeton, N.J.; CDL:093584-D)

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00037471 Kretchmar, B. (1972) Report to American Cyanamid: Acute Oral Toxicity Studies with Two Samples in Female Albino Rats: IBT No. A1373. (Unpublished study received Apr 9, 11973 under 3G1340; prepared by Industrial Bio-Test Laboratories, Inc., submitted by American Cyanamid Co., Princeton, N.J.; CDL:093584-G)

00037472 Smith, J.H.; Rosselet, C.; Cannelongo, B.; et al. (1972) A Neurotoxicity Study of AC 92,100, an Organic Phosphate Cholinesterase Inhibitor, in Hens: Project No. 72S-788. (Unpublished study received Apr 9, 1973 under 3G1340; prepared by Bio/dynamics, Inc. submitted by American Cyanamid Co., Princeton, N.J.; CDL: 093584-H)

00037473 Smith, J.M.; Kasner, J. (1972) Status Report for American Cyanamid Company, November 28, 1972: A Three Generation Reproduction Study of AC 92,100 in Rats: Project No. 71R-727. (Unpublished study received Apr 9, 1973 under 3G1340; prepared by Bio/dynamics, Inc., submitted by American Cyanamid Co., Princeton, N.J.; CDL:093584-I)

00037483 Sleight, B.H., III (1972) The Acute Toxicity of Cycocel"(R) and Experimental Insecticide AC 92,100 to Bluegill (Lepomis maclished study received Apr 9, 1973 under 3G1340; prepared by Bionomics, Inc., submitted by American Cyanamid Co., Princeton, N.J.; CDL:093584-U)

00039018 American Cyanamid Company (1974) General Summary: Counter Related Residues in Immature Corn Commodities from In-Furrow Application of Counter"(R) 15G Soil Insecticide at Planting. Summary of studies 094895-D through 094895-G. (Unpublished study received 1976 under 6F1657; CDL:094895-C)

00040385 American Cyanamid Company (19??) Name, Chemical Identity and Composition of Counter"(R) Soil Insecticide. (Unpublished study received May 1, 1974 under 4F1496; CDL:093978-A)

00040388 American Cyanamid Company (1973) Gas Liquid Chromatography Assay of CL 92,100 Technical Material. Method M-399 dated Mar 7, 1973. (Unpublished study received May 1, 1974 under 4F1496; CDL: 093978-D)

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APPENDIX III-2 *OMB Approval No. 2000-0468 (Expires 12-31-83)*

FIFRA SECTION 3(C)(2)(B) SUMMARY SHEET

EPA REGISTRATION NO.

PRODUCT NAME

APPLICANT'S NAME

DATE GUIDANCE DOCUMENT ISSUED

With respect to the requirement to submit "generic" data imposed by the FIFRA section 3(C)(2)(B) notice contained in the referenced Guidance Document, I am responding in the following manner:

☐ 1. I will submit data in a timely manner to satisfy the following requirements. If the test procedures I will use deviate from (or are not specified in) the Registration Guidelines or the Protocols contained in the Reports of Expert Groups to the Chemicals Group, OECD Chemicals Testing Programme, I enclose the protocols that I will use:

☐ 2. I have entered into an agreement with one or more other registrants under FIFRA section 3(C)(2)(B)(ii) to satisfy the following data requirements. The tests, and any required protocols, will be submitted to EPA by:

NAME OF OTHER REGISTRANT

☐ 3. I enclose a completed "Certification of Attempt to Enter Into an Agreement with Other Registrants for Development of Data" with respect to the following data requirements:

☐ 4. I request that you amend my registration by deleting the following uses (this option is not available to applicants for new products):

☐ 5. I request voluntary cancellation of the registration of this product. (This option is not available to applicants for new products.)

REGISTRANT'S AUTHORIZED REPRESENTATIVE	SIGNATURE	DATE

EPA Form 8580-1 (10-82)

APPENDIX III-3

OMB Approval No. 2000-0468 (Expires: 12-31-83)

CERTIFICATION OF ATTEMPT TO ENTER INTO AN AGREEMENT WITH OTHER REGISTRANTS FOR DEVELOPMENT OF DATA

(To qualify, certify ALL four items)

1. I am duly authorized to represent the following firm(s) who are subject to the requirements of a Notice under FIFRA Section 3(c)(2)(B) contained in a Guidance Document to submit data concerning the active ingredient:

GUIDANCE DOCUMENT DATE

ACTIVE INGREDIENT

NAME OF FIRM	EPA COMPANY NUMBER

(This firm or group of firms is referred to below as "my firm".)

2. My firm is willing to develop and submit the data as required by that Notice, if necessary. However, my firm would prefer to enter into an agreement with one or more other registrants to develop jointly, or to share in the cost of developing, the following required items or data:

3. My firm has offered in writing to enter into such an agreement. Copies of the offers are attached. That offer was irrevocable and included an offer to be bound by an arbitration decision under FIFRA Section 3(c)(2)(B)(iii) if final agreement on all terms could not be reached otherwise. This offer was made to the following firm(s) on the following date(s):

NAME OF FIRM	DATE OF OFFER

However, none of those firm(s) accepted my offer.

4. My firm requests that EPA not suspend the registration(s) of my firm's product(s), if any of the firms named in paragraph (3) above have agreed to submit the data listed in paragraph (2) above in accordance with the Notice. I understand EPA will promptly inform me whether my firm must submit data to avoid suspension of its registration(s) under FIFRA Section 3(c)(2)(B). (This statement does not apply to applicants for new products.) I give EPA permission to disclose this statement upon request.

TYPED NAME	SIGNATURE	DATE

EPA Form 8580-6 (10-82)

PRODUCT SPECIFIC DATA REPORT

EPA Registration No.________________Guidance Document for________________________

Date________________________

Registration Guideline No.	Name of Test	Test not required for my product listed above (check below)	I am complying with data requirements by		(For EPA Use Only) Accession Numbers Assigned
			Citing MRID#	Submitting Data (Attached)	
§158.20 PRODUCT CHEMISTRY					
61-1	Identity of ingredients				
61-2	Statement of composition				
61-3	Discussion of formation of ingredients				
62-1	Preliminary analysis				
62-2	Certification of limits				
62-3	Analytical methods for enforcement limits				
63-2	Color				
63-3	Physical state				
63-4	Odor				
63-5	Melting point				
63-6	Boiling point				
63-7	Density, bulk-density, or specific gravity				
63-8	Solubility				
63-9	Vapor pressure				
63-10	Dissociation constant				

PRODUCT SPECIFIC DATA REPORT

EPA Registration No.________________Guidance Document for______________________________

Date______________________________

Registration Guideline No.	Name of Test	Test not required for my product listed above (check below)	I am complying with data requirements by		(For EPA Use Only) Accession Numbers Assigned
			Citing MRID#	Submitting Data (Attached)	
63-12	pH				
63-13	Stability				
63-14	Oxidizing/reducing reaction				
63-15	Flammability				
63-16	Explodability				
63-17	Storage stability				
63-18	Viscosity				
63-19	Miscibility				
63-20	Corrosion characteristics				
63-21	Dielectric breakdown voltage				
§158.135 TOXICOLOGY					
81-1	Acute oral LD-50, rat				
81-2	Acute dermal LD-50				
81-3	Acute inhalation, LC-50 rat				
81-4	Primary eye irritation, rabbit				
81-5	Primary dermal irritation				
81-6	Dermal sensitization				

APPENDIX V-2

LABELING REQUIREMENTS OF THE FIFRA, AS AMENDED (REFER TO THE SAMPLE LABELS FOLLOWING)

ITEM	LABEL ELEMENT	APPLICABILITY OF REQUIREMENT	PLACEMENT ON LABEL		COMMENTS
			REQUIRED	PREFERRED	
		117	44		
1	Product name	All products	Front panel	Center front panel	
2	Company name and address	All products	None	Bottom front panel or end of label text	If registrant is not the producer, must be qualified by "Packed for . . .," "Distributed by. . .," etc.
3	Net contents	All products	None	Bottom front panel or end of label text	May be in metric units in addition to U.S. units
4	EPA Est. No.	All products	None	Front panel	Must be in similar type size and run parallel to other type.
5	EPA Reg. No.	All products	None	Front panel, immediately before or following Reg. No.	May appear on the container instead of the label.
6A	Ingredients statement	All products	Front panel	Immediately following product name	Text must run parallel with other text on the panel.
6B	Pounds/gallon statement	Liquid products where dosage given as lbs. ai/unit area	Front panel	Directly below the main ingredients statement	
7	Front panel precautionary statements	All products	Front panel		All front panel precautionary statements must be grouped together, preferably blocked.
7A	Keep Out of Reach of Children (Child hazard warning)	All products	Front panel	Above signal word	Note type size requirements.
7B	Signal word	All products	Front panel	Immediately below child hazard warning	Note type size requirements.

ITEM	LABEL ELEMENT	APPLICABILITY OF REQUIREMENT	PLACEMENT ON LABEL		COMMENTS
			REQUIRED	PREFERRED	
7C	Skull & crossbones and word POISON (in red)	All products which are Category I based on oral, dermal, or inhalation toxicity	Front panel	Both in close proximity to signal word	
7D	Statement of practical treatment	All products in Categories I, II, and III	Category I: Front panel unless referral statement is used. Others: Grouped with side panel precautionary statements.	Front panel for all.	
7E	Referral statement	All products where precautionary labeling appears on other than front panel.	Front panel		
8	Side/back panel precautionary statements	All products	None	Top or side of back panel preceding directions for use	Must be grouped under the headings in 8A, 8B, and 8C; preferably blocked.
8A	Hazards to humans and domestic animals	All products in Categories I, II, and III	None	Same as above	Must be preceded by appropriate signal word.
8B	Environmental hazards	All products	None	Same as above	Environmental hazards include bee caution where applicable.

ITEM	LABEL ELEMENT	APPLICABILITY OF REQUIREMENT	PLACEMENT ON LABEL		COMMENTS
			REQUIRED	PREFERRED	
8C	Physical or chemical hazards	All pressurized products, others with flash points under 150°F	None	Same as above	
9A	Restricted block	All restricted products	Top center of front panel	Preferably blocked	Includes a statement of the terms of restriction. The words "RESTRICTED USE PESTICIDE" must be same type size as signal word.
9C	Misuse statement	All products	Immediately following statement of classification or ahead of directions for use		
10A	Re-entry statement	All cholinesterase inhibitors	In the directions for use	Immediately after misuse statement	
10C	Storage and disposal block	All products	In the directions for use	Immediately before specific directions for use or at the end of directions for use	Must be set apart and clearly distinguishable from from other directions for use.
10D U.S.	Directions for use	All products	None	None	May be in metric as well as U.S. units

STORAGE AND DISPOSAL INSTRUCTIONS FOR PESTICIDES

All products are required to bear specific label instructions about storage and disposal. Storage and disposal instructions must be grouped together in the directions for use portion of the label under the heading STORAGE AND DISPOSAL. Products intended solely for domestic use need not include the heading "STORAGE AND DISPOSAL." The STORAGE AND DISPOSAL heading must appear in the minimum type size listed below:

Size of label front panel in square inches	Required type size for the heading STORAGE AND DISPOSAL (all capitals)
10 and under	.6 point
Above 10 to 15	.8 point
Above 15 to 30	10 point
Over 30.	12 point

Storage and disposal instructions must be set apart and clearly distinguishable from other directions for use. Blocking storage and disposal statements with a solid line is suggested as a means of increasing their prominence.

A. Storage Instructions:

All product labels are required to have appropriate storage instructions. Specific storage instructions are not prescribed. Each registrant must develop his own storage instructions, considering, when applicable, the following factors:

1. Conditions of storage that might alter the composition or usefulness of the pesticide. Examples could be temperature extremes, excessive moisture or humidity, heat, sunlight, friction, or contaminating substances or media.

2. Physical requirements of storage which might adversely affect the container of the product and its ability to continue to function properly. Requirements might include positioning of the container in storage, storage or damage due to stacking, penetration of moisture, and ability to withstand shock or friction.

3. Specifications for handling the pesticide container, including movement of container within the storage area, proper opening and closing procedures (particularly for opened containers), and measures to minimize exposure while opening or closing container.

4. Instructions on what to do if the container is damaged in any way, or if the pesticide is leaking or has been spilled, and precautions to minimize exposure if damage occurs.

5. General precautions concerning locked storage, storage in original container only, and separation of pesticides during storage to prevent cross-contamination of other pesticides, fertilizer, food, and feed.

6. General storage instructions for household products should emphasize storage in original container and placement in locked storage areas.

B. Pesticide Disposal Instructions:

The label of all products, except those intended solely for domestic use, must bear explicit instructions about pesticide disposal. The statements listed below contain the exact wording that must appear on the label of these products:

1. The labels of all products, except domestic use, must contain the statement, "Do not contaminate water, food, or feed by storage or disposal."

2. Except those products intended solely for domestic use, the labels of all products that contain active ingredients appearing on the "Acutely Hazardous" Commercial Pesticide Products List (RCRA "E" List) at the end of this appendix or are assigned to Toxicity Category I on the basis of oral or dermal toxicity, skin or eye irritation potential, or Toxicity Category I or II on the basis of acute inhalation toxicity must bear the following pesticide disposal statement:

   "Pesticide wastes are acutely hazardous. Improper disposal of excess pesticide, spray mixture, or rinsate is a violation of Federal Law. If these wastes cannot be disposed of by use according to label instructions, contact your State Pesticide or Environmental Control Agency, or the Hazardous Waste representative at the nearest EPA Regional Office for guidance."

The labels of all products, except those intended for domestic use, containing active or inert ingredients that appear on the "Toxic" Commercial Pesticide Products List (RCRA "F" List) at the end of this appendix or presently meet any of the criteria in Subpart C, 40 CFR 261 for a hazardous waste must bear the following pesticide disposal statement:

"Pesticide wastes are toxic. Improper disposal of excess pesticide, spray mixture, or rinsate is a violation of Federal Law. If these wastes cannot be disposed of by use according to label instructions, contact your State Pesticide or Environmental Control Agency, or the Hazardous Waste representative at the nearest EPA Regional Office for guidance."

Labels for all other products, except those intended for domestic use, must bear the following pesticide disposal statement:

"Wastes resulting from the use of this product may be disposed of on site or at an approved waste disposal facility."

3. Products intended for domestic use only must bear the following disposal statement: "Securely wrap original container in several layers of newspaper and discard in trash."

C. Container Disposal Instructions

The label of each product must bear container disposal instructions appropriate to the type of container.

1. All products intended for domestic use must bear one of the following container disposal statements:

Container Type	Statement
Non-aerosol products (bottles, cans, jars)	Do not reuse container (bottle, can, jar). Rinse thoroughly before discarding in trash.
Non-aerosol products (bags)	Do not reuse bag. Discard bag in trash.
Aerosol products	Replace cap and discard containers in trash. Do not incinerate or puncture.

2. The labels for all other products must bear container disposal instructions, based on container type, listed below:

Container Type	Statement
Metal containers (non-aerosol)	Triple rinse (or equivalent). Then offer for recycling or reconditioning, or puncture and dispose of in a sanitary landfill, or by other procedures approved by state and local authorities.
Plastic containers	Triple rinse (or equivalent). Then offer for recycling or reconditioning, or puncture and dispose of in a sanitary landfill, or incineration, or, if allowed by state and local authorities, by burning. If burned, stay out of smoke.
Glass containers	Triple rinse (or equivalent). Then dispose of in a sanitary landfill or by other approved state and local procedures.

Container Type	Statement
Fiber drums with liners	Completely empty liner by shaking and tapping sides and bottom to loosen clinging particles. Empty residue into application equipment. Then dispose of liner in a sanitary landfill or by incineration if allowed by state and local authorities. If drum is contaminated and cannot be reused[1], dispose of in the same manner.
Paper and plastic bags	Completely empty bag into application equipment. Then dispose of empty bag in a sanitary landfill or by incineration, or, if allowed by State and local authorities, by burning. If burned, stay out of smoke.
Compressed gas cylinders	Return empty cylinder for reuse (or similar wording).

[1] Manufacturer may replace this phrase with one indicating whether and how fiber drum may be reused.

3. The labels for all other products must bear container disposal instructions, based on container type, listed on the first page of this Appendix.

Pesticides that are hazardous wastes under 40 CFR 261.33(e) and (f) when discarded.

"Acutely Hazardous" Commercial Pesticides (RCRA "E" List)
Active Ingredients, (no inerts):

Acrolein
Aldicarb
Aldrin
Allyl alcohol
Aluminum phosphide
4-Aminopyridine
Arsenic acid
Arsenic pentoxide
Arsenic trioxide
Calcium cyanide
Carbon disulfide
p-Chloroaniline
Cyanides (soluble cyanide salts, not specified elsewere)
Cyanogen chloride
2-Cyclohexyl-4,6-dinitrophenol
Dieldrin
0,0-Diethyl S-[2-ethylthio)ethyl] phosphorodithioate
    (disulfoton, Di-Syston)
0,0-Diethyl 0-pyrazinyl phosphorothioate (Zinophos)
Dimethoate
0,0-Dimethyl 0-p-nitrophenyl phosphorothioate (methyl parathion)
4,6-Dinitro-o-cresol and salts
4,6-Dinitro-o-cyclohexylphenol
2,4 Dinitrophenol
Dinoseb
Endosulfan
Endothall
Endrin
Famphur
Fluoroacetamide
Heptachlor
Hexanethyl tetraphosphate
Hydrocyanic acid
Hydrogen cyanide
Methomyl
alpha-Naphthylthiourea (ANTU)
Nicotine and salts
Octamethylpyrophosphoramide (OMPA, schradan)
Parathion

"Acutely Hazardous" Commercial Pesticides (RCRA "E" List) Active Ingredients continued:

Phenylmercuric acetate (PMA)
Phorate
Potassium cyanide
Propargyl alcohol
Sodium azide
Sodium cyanide
Sodium fluoroacetate
Strychnine and salts
0,0,0,0-Tetraethyl dithiopyrophosphate (sulfotepp)
Tetraethyl pyrophosphate
Thallium sulfate
Thiofanox
Toxaphene
Warfarin
Zinc phosphide

There are currently no inert ingredients for commercial pesticides on the "Acutely Hazardous" List (RCRA "E" List).

"Toxic" Commercial Pesticide Products (RCRA "F" List) Active Ingredients:

Acetone
Acrylonitrile
Amitrole
Benzene
Bis(2-ethylhexyl)pthalate
Cacodylic acid
Carbon tetrachloride
Chloral (hydrate)
Chlordane (technical)
Chlorobenzene
4-Chloro-m-cresol
Chloroform
o-Chlorophenol
4-Chloro-o-toluidine hydrochloride
Creosote
Cresylic acid
Cyclohexane
Decachlorooctahydro-1,3,4-metheno-2H-cyclobuta[c,d]-pentalen-2-one
    (kepone, chlordecone)
1,2-Dibromo-3-chloropropane (DBCP)
Dibutyl phthalate
S-3,3-(Dichloroallyl diisopropylthiocarbamate (diallate, Avadex)
o-Dichlorobenzene
p-Dichlorobenzene
Dichlorodifluoromethane (Freon 12®)
3,5-Dichloro-N-(1,1-dimethyl-2-propynyl) benzamide (pronamide,Kerb)
Dichloro diphenyl dichloroethane (DDD)
Dichloro diphenyl trichloroethane (DDT)
Dichlorethyl ether
2,4-Dichlorophenoxyacetic, esters and salts (2,4-D)
1,2-Dichloropropane
1,3-Dichloropropane (Telone)
Dimethyl phthalate
Ethyl acetate
Ethyl 4,4'-dichlorobenzilate (chlorobenzilate)
Ethylene dibromide (EDB)
Ethylene dichloride
Ethylene oxide
Formaldehyde
Furfural
Hexachlorobenzene
Hexachlorocyclopentadiene
Hexachloroethane
Hydrofluoric acid

Appendix V-5
(continued)

"Toxic" Commercial Pesticide Products (RCRA "F" List)
Active Ingredients:

Isobutyl alcohol
Lead acetate
Lindane
Maleic hydrazide
Mercury
Methyl alcohol
Methyl bromide
Methyl chloride
2,2'-Methylenebis (3,4,6-trichlorophenol) (hexachlorophene)
Methylene chloride
Methyl ethyl ketone
4-Methyl-2-pentanone (methyl isobutyl ketone)
Naphthalene
Nitrobenzene
p-Nitrophenol
Pentachloroethane
Pentachloronitrobenzene (PCNB)
Pentaclorophenol
Phenol
Phosphorodithioic acid, 0,0-diethyl, methyl ester
Propylene dichloride
Pyridine
Resorcinol
Safrole
Selenium disulfide
Silvex
1,2,4,5-Tetrachlorobenzene
1,1,2,2-Tetrachloroethane
Tetrachloroethylene
2,3,4,6-Tetrachlorophenol
Thiram
Toluene
1,1,1-Trichloroethane
Trichloroethylene
Trichloromonofluoromethane (Freon 11®)
2,4,5-Trichlorophenol
2,4,6-Trichlorophenol
2,4,5-Trichlorophenoxyacetic acid (2,4,5-T)
Xylene

"Toxic" Commercial Pesticide Products (RCRA "F" List) Inert Ingredients:

Acetone
Acetonitrile
Acetophenone
Acrylic acid
Aniline
Benzene
Chlorobenzene
Chloroform
Cyclohexane
Cyclohexanone
Dichlorodifluoromethane (Freon 12®)
Diethyl phthalate
Dimethylamine
Dimethyl phthalate
1,4-Dioxane
Ethylene oxide
Formaldehyde
Formic acid
Isobutyl alcohol
Meleic anhydride
Methyl alcohol (methanol)
Methyl ethyl ketone
Methyl methacrylate
Naphthalene
Saccharin and salts
Thiourea
Toluene
1,1,1-Trichloroethane
1,1,2-Trichloroethane
Trichlorofluoromethane (Freon 11®
Vinyl chloride
Xylene

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

OFFICE OF
PESTICIDES AND TOXIC SUBSTANCES

CERTIFIED MAIL

SUBJECT: Initiation of Reregistration Process for Pesticide Products Containing Terbufos as the Single Active Ingredient

Dear Registrant:

In accordance with the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), as amended, EPA's Office of Pesticide Programs has begun the reregistration process for pesticide products containing the subject ingredient. Significant changes to the statute were made in 1972, 1975, and 1978; thus, current requirements may be substantially different from those in effect at the time your product(s) were registered. The first phase of reregistration requires that you (1) make a commitment to the Agency regarding data development and (2) subsequently submit revised product labeling and associated information.

This mailing contains the Guidance Document for preparation of submissions, as well as a listing of your affected product(s) (Attachment A), and a separate list of registrants with products subject to this standard and which contain this active ingredient (Attachment B). The latter list is for the purpose of cooperative data development.

The Guidance Document sets out the Agency's evaluation of all available data pertaining to the subject chemical and its registered uses, and its rationale for the regulatory actions being taken at this time. Additionally, the Guidance Document contains instructions describing certain of the steps you must take to maintain registration for your product(s). Products not brought into compliance with the Guidance Document as supplemented by subsequent information from EPA about compliance with certain data support requirements will be subject to suspension and/or cancellation.

Specifically, the enclosed Guidance Document does the following:

1. Introduces the purpose of this document.
2. Explains the Agency's policy regarding data submission and identifies, in table format, the data that must be submitted to complete the Agency's evaluation of each product. In addition, a bibliography identifying the data which is considered part of the data base supporting the registration standard is included.
3. Sets out time-frames for submission of required data.
4. Explains how to revise labeling for maufacturing use products. (As the Guidance Document explains, labeling is not required at this time.)
5. Provides submission instructions.

Because of the variety and complexity of the requirements, and the short statutory time-frames available for certain actions, it is essential that you understand the specific requirements and procedures in order that you may respond in a correct and timely manner. Since a part of these requirements is under Section 3(c)(2)(B) of FIFRA, your first response may be required within 90 days from receipt of this letter. Please note that if you do not respond or do not comply fully with the requirements, your application may be rejected or your product registration cancelled or suspended.

If, after reviewing this material, you do not understand what you must do or how or when you must respond, please contact the Product Manager listed below who will assist you in every reasonable way. If you wish to discuss the data requirements or request that certain data be waived, you must write to the Agency and indicate those data requirements with which you take issue and your rationale for doing so. After the Agency has had a chance to review your submission, the Product Manager will contact you to set up a meeting for the purpose of resolving all issues relative to data requirements.

Please note that this guidance document will eventually be supplemented by EPA with additional information about compliance with data support requirements. In Monsanto v. Administrator, EPA was recently enjoined by the District Court for the Eastern District of Missouri from implementing in any way the "mandatory data licensing" aspects of §3(c)(1)(D) of FIFRA. EPA is assessing the implications of the injunction for the reregistration process. Because of this unresolved situation, EPA has decided to proceed with the requirements in this guidance package which do not relate to the "data licensing" issue and to supplement the package with additional guidance when circumstances permit.

If you have any questions concerning this Guidance Document, you may contact the Product Manager listed below:

Mr. William H. Miller (Product Manager 16)
Registration Division (TS-767)
Office of Pesticide Programs
Environmental Protection Agency
Washington, D.C. 20460
Telephone: 703/557-2600

Sincerely,

Douglas D. Campt, Director
Registration Division (TS-767)

Enclosure

ATTACHMENT A

PRODUCTS AFFECTED BY THIS REREGISTRATION PROCESS

Following is a list of your products affected by this reregistration process. If this list is incomplete or inaccurate in any way, please notify the Product Manager (PM) identified in the letter.

ATTACHMENT B

REGISTRANTS WITH PESTICIDE PRODUCTS CONTAINING THE ACTIVE INGREDIENT

The information attached will allow registrants with pesticide products containing the above ingredient to contact one another regarding joint data development or sharing the cost of data development under section 3(c)(2)(B) of FIFRA. This information includes the following: EPA Reg. No., company name, company address, active ingredient, percentage of active ingredient and type of formulation, such as Manufacturing-Use Product (MP), Technical Product (TP), Wettable Powder (WP), and Emulsifiable Concentrate (EC).